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8	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA	
10		Case No. 3:23-cv-05316-SI
11	EDWARD ALLYN HUDACKO	Cuse 110. 5.25 CV 05510 SI
12	Disintiff	SECOND AMENDED COMPLAINT
13	Plaintiff,	FOR DAMAGES
14	V.	1) 42 U.S.C. § Deprivation of
15	STEPHEN ROSENTHAL, MD;	Fundamental Right to Direct a Minor Child's Medical Care
16	JANET YI MAN LEE, MD; DIANE	Without Due Process and
17	EHRENSAFT, PHD; ASAF ORR;	Conspiracy to Same
18	NATHANIEL BIGGER; DANIEL HARKINS; CHRISTINE	2) Fraud by Concealment
19	UNDERHILL; and DOES 1-100,	3) Negligence – Infliction of Emotional Distress
20		Directional Distress
21	Defendants.	DEMAND FOR JURY TRIAL
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Plaintiff Edward Allyn Hudacko ("Hudacko") brings this action to enforce his fundamental constitutional rights and seeks compensation for constitutional, emotional and financial injuries inflicted upon him when Defendants performed a life-altering, highly experimental gender-identity related surgery on his minor son without his consent. Plaintiff alleges as follows:

CASE SUMMARY

- 1. Hudacko's right to prohibit any gender identity related surgery on his son is a fundamental constitutional right arising under the Liberty Clause of the Fourteenth Amendment to the United States Constitution.
- 2. Plaintiff's fundamental right was explicitly reiterated in an August 2020 Court-Ordered Injunction that prohibited any gender-identity related surgery on his then minor son S.H. without Hudacko's consent ("NO SURGERY INJUNCTION").
- 3. As part of a joint agreement between Defendants that Plaintiff was not aware of until it was too late, a Supprelin Implant was surgically implanted into S.H. as a form of "hormone therapy", as part of so-called "gender affirming care." Such use of Supprelin is for the purpose of stopping adolescent puberty which is off label use and was done without the consent of Plaintiff. ("CONSPIRACY or SCHEME")
- 4. Like all forms of so-called "gender-affirming care" use of the Supprelin Implant constitutes medical experimentation. Without informed consent, such experimentation on minors violates both federal and state laws.
- 5. As detailed herein, the entire transgender industry that promotes "gender affirming care" is predicated on dishonest indeed fraudulent set of assertions that such form of medical care is "safe, effective, and medically necessary" for minors who suffer from the DSM 5 recognized medical condition of "gender dysphoria", or those actually suffering from gender-related stress, when in fact recent reports show that it is when in fact use of such procedures or any stage of gender affirming care is medically dangerous to minors.

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- 6. Defendants Stephan Rosenthal (co-director of the clinic that offered "gender affirming care" to Hudacko's son), Diane Ehrensaft (psychologist and the other clinic codirector who helped convince Hudacko's son and the Defendant Underhill that "gender affirming care" was necessary, safe and effective), and Janet Lee (the surgeon who performed the surgery) are all members of the World Professional Association for Transgender Health ("WPATH").
- 7. WPATH presents itself as a 501(c)(3) educational and scientific nonprofit dedicated to using the principles of "Evidence Based Medicine" to establish the "standard of care" for "treatment" of transgender and gender non-conforming people.
- However, WPATH is actually a pseudo-scientific political advocacy organization whose ulterior motives are to maximum revenue for its members and associated organizations (both nonprofit and for-profit), and has a goal of maximizing the numbers of vulnerable people – especially children –enrolled in various human medical experiments, under the guise of routine, "medically necessary treatment."
- As part of their standard operating procedure, members of WPATH, including Defendants Rosenthal, Ehresnsaft, and Lee (collectively the "WPATH Defendants") knowingly make false and misleading claims about the purported necessity, safety and efficacy of "gender affirming care" on children. As defined below, this standard set of false and misleading claims is herein referred to as the PLAYBOOK.
- 10. The WPATH Defendants recite from the PLAYBOOK, i.e. make these deceptive claims in public, and in their private consultations with their potential lucrative patients to turn them into unwitting experimental subjects.
- 11. Utilizing standard deception from the PLAYBOOK, the WPATH Defendants succeeded in persuading both the minor child S.H. and his mother (Defendant Underhill) that "gender affirming care" was necessary, safe and effective treatment for the child's alleged case of "gender dysphoria." In reliance on the truth of the contentions of the WPATH defendants, to her detriment, Underhill gave consent for the Supprelin® Implant

- surgery, after previously consenting to other forms of puberty suppression without informing Hudacko at any time in violation of his fundamental rights.
- 12. At all relevant times as alleged herein, the WPATH Defendants knew that suppressing puberty in children has never been proven effective for treating the psychological condition of gender dysphoria. WPATH Defendants also knew that suppressing puberty in males is known to stunt growth, prevent the skeleton and bone density from developing normally because testosterone is needed to increase bone density during adolescence, leading to a greatly increased risk of osteoporosis.
- 13. WPATH Defendants also knew that suppressing puberty is known to inhibit brain development during critical windows of opportunity. Suppressing puberty is known (or at minimum is strongly suspected) to have permanent, irreversible negative effects on mental function, including IQ and executive function.
- 14. WPATH Defendants executed the PLAYBOOK, and deliberately concealed the lack of any high-quality evidence showing gender affirming care to be even remotely effective, and concealed a litany of known and strongly suspected negative consequences.
- 15. WPATH Defendants deliberately concealed the fact that, like so many others, Hudacko's son was unwittingly enrolled in the EXPERIMENT, i.e. the ongoing human medical experimentation, funded by the NIH, that purportedly seeks to learn what the long-term effects of gender-affirming care actually are.
- 16. Had Underhill known that "gender-affirming care" was not safe and not effective, had life altering damaging effects, or had she known that the TRUE WPATH MISSION includes enrolling unwitting experimental subjects under the false pretense that gender affirming care is necessary, safe and effective "treatment," she likely would not have consented.
- 17. Defendant Asaf Orr is a lawyer who advises the WPATH DEFENDANTS, and advances the TRUE WPATH MISSION by teaching (along with the former judge in the Hudacko FAMILY LAW CASE Joni Hiramoto) the talking points from the PLAYBOOK

to minor's counsels across California if not the United States, including but not limited to Defendant Daniel Harkins, S.H's minor's counsel in the family law case.

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18. Defendants formulated, concealed and executed a plan to perform gender identity related surgery on the minor child S.H. without the necessary and legally required informed consent.

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19. Plaintiff has commenced this action because Defendants are liable for violating 6 7 Hudacko's civil rights, and/or alternatively, for Fraud by Concealment, and/or Infliction of

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PARTIES

Plaintiff Α.

Emotional Distress.

20. Plaintiff Edward Allyn Hudacko ("Hudacko") is the father of the minor child S.H., and former husband to Defendant Christine Underhill f/k/a Christine Hudacko, who at all times opposed any form of "gender affirming care" on his son, including but not limited to, any form of puberty blockers or opposite sex hormones as well as any attempts to "transition" the minor child from being a boy into being a girl.

B. **Defendants**

21. **Defendant Stephen Rosenthal, MD - ("ROSENTHAL")** is a state-sponsored licensed medical doctor who specializes in endocrinology who is employed by the University of California at San Francisco ("UCSF"), is a co-director of a Child and Adolescent Gender Center, a Past President of the Pediatric Endocrine Society, a principal investigator in various NIH-funded human medical experiments involving gender affirming care on minors, and a member of WPATH who acted under color of law to advance the TRUE WPATH AGENDA employing the PLAYBOOK in support of the conspiracy and SCHEME with the other Defendants to persuade the minor child's mother to unwittingly consent to GENDER AFFIRMING CARE, thus subjecting the child to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION, with a reckless disregard for the constitutional rights and emotional distress of Plaintiff, the child's father.

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- 22. **Defendant Janet Yi Man Lee, MD** ("LEE") is a state-sponsored licensed medical doctor specializing in pediatric endocrinology who is employed by UCSF, a surgeon and a member of WPATH, who acting under color of law, helped advance and employ the TRUE WPATH AGENDA via its PLAYBOOK in support of the conspiracy and SCHEME to persuade Defendant Underhill to unwittingly consent to GENDER AFFIRMING CARE, thus subjecting S.H. to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION, with a reckless disregard for the constitutional rights and emotional distress of Plaintiff, the child's father.
- 23. **Diane Ehrensaft, PhD** ("EHRENSAFT") a state-sponsored developmental clinical psychologist who is employed by UCSF, and a member of WPATH who acted under color of law to advance the TRUE WPATH AGENDA by employing its PLAYBOOK in support of the conspiracy and SCHEME to persuade S.H.'s mother to unwittingly consent to GENDER AFFIRMING CARE, thus subjecting the child to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION, with a reckless disregard for the constitutional rights and emotional distress of Plaintiff, the child's father.
- 24. **Defendant Asaf Orr** ("ORR") is a licensed California attorney, transgender activist and at all relevant times the Legal Director of Child and Adolescent Gender Center, who participated in the coordination of the Supprelin surgery on S.H. without the consent of Plaintiff, who helped advance the TRUE WPATH AGENDA by teaching minor's counsels including but not limited to Defendant Daniel Harkins to represent "transgender kids" in such fashion as to execute the PLAYBOOK, striving to maximize the enrollment of minors into medical experimentation that is gender affirming care.
- 25. **Defendant Nathaniel Bigger (**"BIGGER") is a licensed California attorney and at all relevant times the attorney representing Underhill in the FAMILY LAW CASE, who, acting as *de facto* agent of WPATH DEFENDANTS and in conformity with the TRUE WPATH MISSION, participated in a conspiracy with the other Defendants and a SCHEME by accepting money in exchange for advising Underhill according to the PLAYBOOK, coordinating the Supprelin surgery on S.H. without the consent of Plaintiff, rather than

advising his client according to the law, the constitution, or the NO SURGERY INJUCTION. Defendant Bigger participated in the conspiracy with the other defendants to, help deceive Underhill into the believing that GENDER AFFIRMING CARE is safe and effective for her son; by falsely telling Underhill that unconsented to gender identity related surgery on a minor was legal; by concealing the fact that Underhill was being tricked consenting to the Minor Child's participation in INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION; and by concealing the SCHEME from Hudacko.

- 26. **Defendant Daniel Harkins** ("HARKINS") is a California attorney and at all relevant times the court-appointed attorney representing Minor Child in the FAMILY LAW CASE, who, acting as *de facto* agent of WPATH DEFENDANTS and in conformity with the TRUE WPATH MISSION, participated in the SCHEME by accepting money in exchange for advising Minor Child according to the PLAYBOOK, coordinating the Supprelin surgery on S.H. without the consent of Plaintiff, rather than acting according to the law as an officer of the court, thus helping to deceive Defendant Underhill and S.H. into believing that GENDER AFFIRMING CARE is safe and effective; and by concealing the fact that Underhill was being tricked into consenting to the Minor Child's participation in INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION; and by concealing the SCHEME from Hudacko.
- 27. **Defendant Christine Underhill** ("UNDERHILL") is the mother of S.H. and Hudacko's ex-wife and, at all times favors attempts to do the impossible -namely "transition" S.H. from being a boy into being a girl, falsely believing that such a thing was possible, and falsely believing that GENDER AFFIRMING CARE is safe & effective, and agreed to and coordinated with the other Defendants to allow the Supprelin surgery on S.H. without the consent of Plaintiff.
- 28. **DOE DEFENDANTS** are presently unknown individuals and/or entities who may also have participated in the SCHEME to coordinating the Supprelin surgery on S.H. without the consent of Plaintiff, to advance the TRUE WPATH MISSION.

II. JURISDICTION

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29. Original federal subject matter jurisdiction is conferred on this Court by 28 U.S.C. §1343(3) and 1343(4), which provide for original jurisdiction in this Court of all suits brought pursuant to 42 U.S.C. §1983. Jurisdiction is also conferred by 28 U.S.C. §1331(a) because claims for relief derive from the United States Constitution and the laws of the United States. Jurisdiction of this Court over any claim for Declaratory Relief is conferred by 28 U.S.C. §2201.

30. This federal court should assert Supplemental Jurisdiction over the state law claims, as they arise from the same nucleus of operative facts giving rise to the federal civil rights claims.

III. **VENUE**

31. Venue properly lies in the Northern District of California, in that the events and circumstances herein alleged occurred in the greater San Francisco Bay area.

IV. **FACTS**

- "GENDER AFFIRMING CARE" refers collectively to the use of social 32. transitioning, and/or puberty blocking hormones, and/or opposite sex hormones, and/or genital surgeries.
- "THE EXPERIMENT" refers to the ongoing effort by the scientific and medical community to learn the long-term physical and mental effects of SOCIAL BLOCKERS, **OPPOSITE-SEX** TRANSITIONING, **PUBERTY** HORMONES, VAGINOPLASTY and other surgeries on minor children. As with most forms of human medical experimentation, voluntary participation for "gender affirming care" would be lowto-non-existent absent the PLAYBOOK and the TRUE WPATH MISSION.
- 34. "TRUE WPATH MISSION" as used herein means (1) maximizing the number of people seeking GENDER AFFIRMING CARE so as to maximize the amount of money received by WPATH members and associated for-profit and nonprofit entities; (2) maximizing the number of human subjects – especially children – unwittingly enrolled into experimental protocols under the guise of medically necessary treatment; and (3) creating

- 13 "WPATH DEFENDANTS" – refers collectively to Stephen Rosenthal, MD; Diane 14 Ehrensaft, PhD; and Janet Lee, MD.
 - 37. "FAMILY LAW CASE" - refers to Contra Costa Superior Court case no. MSD19-05641, Christine Marie Hudacko v. Edward Allyn Hudacko.
 - 38. "NO SURGERY INJUNCTION" – refers to the August 26, 2020 Court Order stating: [The minor child] will not be permitted to undergo any gender **identity related surgery** until they are 18 years of age, absent a written agreement by both parties, Christine Hudacko and Edward Hudacko, or an order of the court.

[Exh. "A", p. 7, emphasis added]

"SCHEME" – refers to the plan executed by Janet Yi Man Lee, MD; Diane Ehrensaft, PhD; Stephen Rosenthal, MD; Asaf Orr; Nathaniel Bigger; Daniel Harkins And Christine Underhill (each of whom knew about the NO SURGERY INJUNCTION) under which gender identity related surgery was performed on the minor child without Hudacko's consent, and which plan included an agreement to conceal the plan from Hudacko until after it was too late. The deception perpetrated in the SCHEME was consistent with the

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PLAYBOOK, while the SCHEME itself was a successful event according to the TRUE WPATH MISSION.

40. "INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION" is any medical study or protocol which violates Health and Safety Code §24170 et seq and the Nuremberg code, § 1, which states in pertinent part:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion, and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

WPATH and the TRUE WPATH MISSION

- 41. The World Professional Association for Transgender Health ("WPATH") is an organization that purports to be dedicated promoting evidence-based care, education, and research in transgender health.
- 42. WPATH periodically publishes "Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People." The most recent version of these "Standards of Care" is version 8, published in 2022 ("SOC-8"). Physicians and mental health providers across the globe rely on SOC-8 for guidance in prescribing puberty blockers, opposite-sex hormones, and various types of surgeries in the treatment of the psychological condition "gender dysphoria."
- 43. In or about January 2024, newly released files from WPATH's internal messaging forum, as well as a leaked internal panel discussion, demonstrate that WPATH is neither scientific nor advocating for ethical medical care. These internal communications reveal

that WPATH advocates for many arbitrary medical practices, including hormonal and surgical experimentation on minors and vulnerable adults.

- 44. Working hand-in-hand advancing the interests of major hospitals and pharmaceutical companies, WPATH's approach to medicine is consumer-driven and pseudoscientific, and its members appear to be engaged in political activism and commercial promotions, not science.
- 45. The TRUE WPATH MISSION is at least three-fold: First, by overstating the alleged risks of "untreated" gender dysphoria or gender related distress, and maximizing the profit of gender clinics by maximizing the number of people especially children and adolescents who seek "gender affirming care." Second, by falsely proclaiming psychological benefits and fraudulently concealing the known and suspected physical and mental harms caused by these procedures, maximize the number of subjects unwittingly enrolled into experimental protocols purportedly studying their long-term effects. Third, to create a population of young adults who are chronologically over 18 (thus legally able to consent to sex), but who physically, mentally and emotionally remain child-like.
- 46. Defendants ROSENTHAL, LEE, and EHRENSAFT are each members of WPATH.
- 47. ROSENTHAL is co-founder and medical director of the multidisciplinary UCSF Child and Adolescent Gender Center (CAGC), where he cares for young transgender patients. Rosenthal has seen close to 2,000 transgender young people with gender dysphoria, with an average of 15-20 new patients per month, ranging in age from 3 to 25 years old.
- 48. Rosenthal is an elected member of the Board of Directors of WPATH, and served on the committee responsible for SOC-8.
- 49. According to a sworn declaration he filed in a federal lawsuit, Rosenthal admits that he is actively serving as a "Principal Investigator" or "Co-Investigator" on "numerous" NIH -funded medical experiments regarding the physical and mental health effects of so-called "gender-affirming care" upon children.

1 | 50. One such ongoing human medical experiment is called "The Impact of Early Medical Treatment in Transgender Youth," operating with a total NIH grant award of \$5,732,531.

- 51. The WPATH DEFENDANTS know that children do not understand the effects of hormone therapy, opposite sex hormones, or medical mutilation surgeries.
- 52. Rosenthal deliberately conceals from his experimental subjects that are minors the fact that they are being subjected to medical procedures that are experimental and banned in some other countries. Instead, Rosenthal misleads these children (and their parents) by reciting from the PLAYBOOK such things as the claim that GENDER AFFIRMING CARE is the "standard of care," clearly suggesting that these procedures are safe & effective under the standards of evidence-based medicine, when (a) there is no high-quality evidence that the procedures are effective at treating the psychological condition of "gender dysphoria, and (b) these procedures are highly dangerous to children to the point of being physically and mentally disabling.
- 53. Rosenthal also recites from the PLAYBOOK the notion that the effects of puberty blockers are reversible. Rosenthal states in his sworn declaration that if puberty blockers are discontinued "the patient's endogenous puberty will resume." [Exh. "Q", ¶ 38]
- 54. During puberty there are critical windows of opportunity for brain development as humans mature from child-like thinking and decision making to adult thinking and decision making. It is simply false to suggest that puberty will "resume." Expert testimony and scientific evidence shows that suspending puberty is likely to halt brain development sufficient to permanently lower IQ and executive function.
- 55. The use of puberty blockers in children diminishes bone density, leading to medically-induced osteoporosis.
- 56. The use a puberty blockers also greatly increases the likelihood of proceeding to the next step of GENDER AFFIRMING CARE, as opposed to returning to a healthy mental belief system that matches their actual biology, namely opposite sex hormones. In males, opposite-sex hormones can lead to decreased muscle mass and strength, decreased sexual desire, inability to achieve orgasm, decreased sperm production, voice changes, decreased

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- testicular volume, erectile dysfunction, infertility, deep vein blood clots, stroke, coronary artery disease, and cerebrovascular disease. Compared to males not treated with opposite sex hormones, males on opposite-sex hormones are times more likely to get breast cancer, twice as likely to have a stroke, 16 times as likely to have deep vein clots. As compared to women, males are two times more likely to have a heart attack.
- 57. WPATH DEFENDANTS at all times relevant herein knew about these medically proven facts and deliberately conceal these facts from the public, and from their patients, the experimental subjects, and from Plaintiff.
- 58. In or about January 2024, Plaintiff obtained a recording of a Continuing Legal Education ("CLE") seminar titled "Gender and Transgender Issues" featuring Asaf Orr and Superior Court judge Joni Hiramoto. The seminar was presented to a group of minor's counsel attorneys. Among others, in attendance was Daniel Harkins, court-appointed attorney for Minor Child. In fact, Daniel Harkins was mentioned in the seminar recording.
- 59. The CLE seminar was clearly intended to advance the TRUE WPATH MISSION with numerous points taken directly from the PLAYBOOK and push the ideas on licensed California attorneys.
- 60. For example, Asaf Orr stated:
 - "[Puberty blockers are] just a pause button so that if you remove the medication, puberty comes back as it was. There's no effect to fertility, no effect to anything."
- 61. Asaf Orr also stated:
 - "Puberty blockers are fully reversible. 100% reversible."
- As with the WPATH DEFENDANTS, Asaf Orr knew at all relevant times that puberty blockers are not fully reversible, that they can affect fertility, and they have other detrimental effects as well.
- 63. Joni Hiramoto, acting in a personal, non-judicial capacity, advanced the TRUE WPATH MISSION by stating:
 - "[These points from the PLAYBOOK are] what you have to tell your judge. What was important to me [as judge in the Hudacko case] was that ... and you'll see that in that minor's report that Dan Harkins did [in

Hudacko's case], he went in and systematically debunked all of the studies that I was given by the parent in opposition [i.e. Hudacko]. And the thing is, if you need help doing that, **you need to talk to Asaf**.

- 64. Judge Hiramoto explained how best to be deceptive:
 - "You [Minor's counsel] may want to, say okay, this is a pro-transition approach, but I think it's better and a little bit more sophisticated to say this is the parent who should be given the decisions in this area because this is the parent who supports the approach that I think is in the child's best interests."
- 65. Both Asaf Orr and Judge Hiramoto make derogatory reference to the "parent in opposition." The clear premise and assumption of the CLE talk is that GENDER AFFIRMING CARE is appropriate and always in the child's best interest.
- 66. The point of the seminar is to teach minor's counsels what to say, i.e. the PLAYBOOK, so that the scientific and medical reality of the dangerous nature of GENDER AFFIRMING CARE (i.e. the "studies") are excluded, and so that the "parent in opposition" always loses.
- 67. Toward the goals of the TRUE WPATH MISSION, Judge Hiramoto asked:

 "Do [parents'] behaviors [i.e. disagreeing with "GENDER
 AFFIRMING CARE"], the things they say, the things they do rise to
 the level of abuse?"
- 68. Clearly Judge Hiramoto and Defendant Orr aimed to imply that severe punishments are available against parents such as Hudacko who dare to oppose the TRUE WPATH MISSION.
- 69. Based on this new information, Plaintiff is informed and believes that Joni Hiramoto is part of the conspiracy to profit by INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION on children.
- 70. Based on this new information, Plaintiff is informed and believes that a discriminatory custom or usage against the parent designated "in Opposition" [to GENDER AFFIRMING CARE] exists in the local jurisdiction where the discrimination against him took place, and in the State, generally. *Adickes v. S.H. Kress & Co.* 398 U.S. 144 (1970) ("*Adickes*")

A. The No Surgery Injunction

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of contention was that Underhill believed that their son – then a minor – suffered from the psychological condition of "gender dysphoria," and wanted to him to medically "transition"

Hudacko and Underhill were embroiled in a high-conflict Family Law case. The point

An August 2020 Court Order awarded Hudacko's ex-wife, Defendant Christine

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their son S.H.'s male appearance to that of a female's appearance.

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Underhill legal custody (thus medical decision-making authority) over the minor child, thus

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stripping Hudacko of most of his fundamental constitutional parental rights. However, the

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Court Order contained an explicit exception to Underhill's medical authority, in the form

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of an injunction, hereafter termed the NO SURGERY INJUNCTION, which states:

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[The minor child] will not be permitted to undergo <u>any</u> gender identity related surgery until they are 18 years of age, absent a written agreement by both parties, Christine [Underhill] and Edward Hudacko, or an order of the court.

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[Exh. "A", p. 7, emphasis added]

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73. Each Defendant knew about the NO SURGERY INJUNCTION, thus knew that any such surgery was prohibited, absent Hudacko's written consent.

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74. Defendant Underhill, the boy's mother, was at all times in favor of GENDER-AFFIRMING CARE for him, believing it was medically necessary.

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75. Believing that the treatments for "gender dysphoria" remain largely experimental, Hudacko was opposed to transgender for the minor child.

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76. The Family Court's August 26, 2020 custody Order contains two provisions speaking to the issue of gender identity related medical procedures – Section 7a and Section 7b. First, at Section 7a, the Order states:

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[Minor Child] shall be permitted to pursue the services provided by UCSF as to the Minor Child's gender identity, and **shall be permitted to commence hormone therapy**, if recommended by UCSF.

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77. The important exception to Underhill's legal custody over the Minor Child is found immediately thereafter, at Section 7b, where the Order issues the NO SURGERY

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INJUNCTION:

[Minor Child] will not be permitted to undergo <u>any</u> gender identity related surgery until they are 18 years of age, absent a written agreement by both parties, Christine Hudacko and Edward Hudacko, or an order of the court.

[Exh. "A", p. 7, emphasis added]

- 78. The Court's NO SURGERY INJUNCTION did not define gender identity surgery nor did it define hormone therapy.
- 79. "Surgery" is statutorily-defined in California as "any act in which human tissue is cut, altered, or otherwise infiltrated by any means." Bus. & Prof. Code § 3041. A Supprelin Implant is "subcutaneous," meaning "administered under the skin." See Merriam-Webster Dictionary, "subcutaneous". Skin is human tissue. Since the implant is administered under the skin, it follows that Supprelin Implant involves cutting or infiltrating human tissue.
- 80. Supprelin Implant ® is a registered trademark of Endo Pharmaceuticals Inc. Endo's published Prescribing Information explicitly states that Supprelin Implant "is a surgical procedure" See Exh. "J"; involves the use of a "surgical tool"; and requires "making the incision" using the "sterile scalpel".
- 81. UCSF billed and was paid \$209,820.34 for the Supprelin Implant surgery done on S.H.. Supprelin Implant was categorized as "SURGERY" on the Claim Detail for the surgery billing.

B. The Scheme to Perform Gender Identity Related Surgery as Part of the TRUE WPATH MISSION

- 82. At all relevant times, including at the time of drafting the original complaint here in October 2023, Hudacko thought that UCSF's policies were operative. Only in January 2024 with the publication of the WPATH FILES did Hudacko discover the facts of regarding what is herein termed the TRUE WPATH MISSION.
- 83. Not knowing the TRUE WPATH MISSION was operative, on 9/29/2020 Hudacko emailed Underhill, informing her that UCSF's policy is to include both parents in meetings regarding gender identity related medical procedures. Later that day, Underhill replied, informing Hudacko that:

UCSF has the court order [including the NO SURGERY INJUNCTION] per their request.

[Exh. "B", p. 7]

- 84. On 10/21/2020, consistent with his right to timely be informed about his Minor Child's medical treatment, Hudacko wrote a letter to REGENTS, Defendants Rosenthal, Ehrensaft, Bigger, and Harkins, copying Underhill's counsel, requesting access to "MyChart," i.e. the Minor Child's online medical records at UCSF. That request was ignored. [Exh. "O", pp. 79-83]
- 85. The 10/21/2020 letter also informed and alerting REGENTS, Defendants Rosenthal, Ehrensaft, Bigger, and Harkins that the custody agreement over the Minor Child from "Judge Hiramoto extended Christine's legal custody ... while continuing to limit decisions over surgical treatment." [Id.]
- 86. The 10/21/2020 letter also made it clear that Hudacko was against gender interventions on his son, questioning Rosenthal's NIH-funded study, raising the question as to whether his son is participating in the NIH-funded study, and if so, queried whether that was beyond the judge's order because his son was involved in an experiment as to medical treatment. [Id.]
- 87. Hudacko directly expressed his worry and opposition to alerting REGENTS, Defendants Rosenthal, Ehrensaft, Bigger, and Harkins placing his son on puberty blockers (gonadotropin releasing hormone agonists (GnRHa), pointing out studies that demonstrate "the lack of consensus among professionals ... of ... *optimal* dosing regimes" as well as potentially cognitive risks to his son. [Id.]
- 88. The clear indication from the 10/21/2020 letter to REGENTS, Defendants Rosenthal, Ehrensaft, Bigger, and Harkins is that Hudacko did not and would never have given consent to his son being placed on puberty blockers, and with the NO SURGERY INJUNCTION was empowered to prevent the surgical insertion of Supprelin but for the conspiracy to surgically insert Supprelin into S.H. behind his back.

- 1 89. Even if Underhill had not provided REGENTS, Defendants Rosenthal, Ehrensaft,
 2 Bigger, and Harkins the NO SURGERY INJUNCTION, the Defendants were on notice of
 3 the court's order.
- 4 90. Upon information and belief, REGENTS maintained that 10/21/2020 letter was received and Defendant Lee had access to it.
- 6 | 91. On 2/17/2021, unbeknownst to Hudacko, Underhill took 16-year-old Minor Child for 7 | a patient visit at UCSF Child and Adolescent Gender Center. UCSF doctors discussed with 8 | Minor Child a category of experimental drugs called "Puberty Blockers" that "help 9 | temporarily suspend or block the physical changes of puberty." [Exh. "E", p. 19]
 - 92. Four different types of puberty blockers (Gonadatropin Releasing Hormone Agonists) were discussed at the 2/17/2021 visit. The first three options were nonsurgical. Two of these are injections (leuprolide acetate and triptorelin); a third is an oral tablet called spironolactone. However, the fourth option a "subcutaneous histrelin implant" required surgery. [*Id*]
 - 93. On 2/17/2021, unbeknownst to Hudacko, UCSF sent a letter to Underhill, following up with that day's visit by [Minor Child] Hudacko (AKA: [Girl Name])." The subject of this letter was "PUBERTAL BLOCKERS," and its purpose was to inform Underhill about the purported risks and benefits of puberty blocking hormones. Of note are UCSF's warnings that the "side effects and safety of puberty blockers are not completely understood," that there "may be long-term risks that are not yet known," and that this "is not approved by the Food and Drug Administration for this specific use." [Exh. "E", pp. 18-21]
 - 94. However, the warnings in the 2/17/2021 letter are vague and deceptive, especially when the patient / subject and his mother have been told, by people in white coats, that PUBERTY BLOCKERS are the "standard of care." "Standard of care" strongly implies "safe & effective." This deception is according to the PLAYBOOK and was employed by all Defendants in the 2/17/21 visit.

- 1 2
- 95. On 2/23/21, Underhill caused the Minor Child to deposit sperm into a sperm bank. [Exh. "K", p. 67] This clearly implies that Defendants knew that GENDER-AFFIRMING
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 - CARE will, in all likelihood, sterilize S.H. for life.
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- 96. It is not possible that S.H. gave informed consent to his sterilization, because children
- 5 don't yet understand what they are sacrificing. They, including S.H., did not understand
- 6 how they may come to want biological children of their own one day, nor do they even
- 7 understand how adoption works or how arduous it can be to conceive a baby via in vitro
- 8 fertilization. S.H. surely did not understand the other ramifications because they were not
 - even discussed by Defendants with Underhill and S.H..
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- 97. In documents leaked as part of the January 2024 WPATH FILES, it has now become
- 11 publicly known that WPATH members are well-aware of the impossibility of a child giving
- 12 informed consent to sterilization. The WPATH DEFENDANTS, who are WPATH
- 13 members, at all relevant times knew of this impossibility.
- 14 98. On information and belief, in reliance on the PLAYBOOK, Underhill gave consent
- 15 for the WPATH DEFENDANTS to sterilize her son. However, she had no right to
- 16 unilaterally do that in violation of Family Code section §6925(b)(1). Only a competent adult
- 17 can consent to their own sterilization.
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- 99. On 6/8/2021, Rosenthal issued "Progress Notes" regarding Minor Child's medical
- 19 procedures to that point in time which evince conversations between Underhill, Harkins,
- 20 Bigger with the WPATH Defendants to agree to conceal Supprelin surgery on S.H. from
- 21 Hudacko, stating in relevant part:
- 22

- Mother and [Minor Child] have separate attorneys who are navigating
- [a] complex family situation [related to the fact that] father is not
- supportive of [Minor Child's] gender care.
- 24
 - [Exh. "G", p. 28]
- 25 100. It is true that Hudacko did not support sterilizing his son, nor subjecting him to
- 26 procedures that have never been shown to be effective at treating the psychological
- 27 condition of "gender dysphoria," but which have instead been shown to have dire
- 28 consequences on both body and mind.

1 101. UCSF's 6/8/2021 progress notes state that that Underhill has "medical [legal] custody." Despite the fact that REGENTS, Rosenthal, Ehrensaft and Orr were given and aware of the NO SURGERY INJUNCTION COURT ORDER and 10/21/2020 letter from Hudacko informing them that Hudacko needed to grant consent for surgeries. Without mentioning Hudacko, UCSF's 6/8/2021 progress notes continues:

"Mother is working with her attorney, Gemma's attorney and Asaf Orr, JD—everyone [except Hudacko] is working together to achieve resolution [of the Minor Child's having been born male] in the near

[Exh. "G", p. 29]

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102. UCSF's 6/8/2021 statement further indicates that:

[Underhill] will keep J. Cohen, LCSW [but not Hudacko] informed of situation.

[Exh. "G", p. 29]

- 13 | 103. The 6/8/2021 statement acknowledged two issues with the proposed surgical procedure: "resolution of insurance issues" because "father is not supportive of [Minor Child's] gender care." [Id.]
 - 104. On 8/4/2021, unbeknownst to Hudacko, after agreeing to do so and conceal the intent to do so, Defendants did cause S.H. to undergo the Supprelin Implant procedure, categorized as "SURGERY." [Exh. "D", p. 16]
- 19 105. UCSF billed and was paid \$209,820.34 for the Supprelin Implant surgery. [Exh. "L", 20 p. 71].
 - 106. As employees of UCSF, Rosenthal, Ehrensaft, Lee and Orr financially benefitted from the Supprelin surgery.
 - 107. Defendants Bigger and Harkins also financially benefited from the Supprelin for their billed time in "resolving" the issue to circumvent Hudacko's consent.
 - 108. Underhill, UCSF, Rosenthal, Ehrensaft, Bigger and Harkins in a "meeting of the minds" all worked in concert with a singular goal namely to have the Supprelin implant surgery occur, be covered by insurance, and be hidden from Hudacko.

109. On 10/8/2021 and again on 10/15/2021, Hudacko and Underhill each attended a football game for their younger son. Twice Hudacko politely asked Underhill about the Minor Child, and twice Underhill refused to discuss the matter, later characterizing inquiry about the Minor Child as "harassing" her. [Exh. "C" p. 14]

110. On 10/18/2021, Underhill emailed Hudacko, revealing the Supprelin Implant, yet clearly wishing to discourage Hudacko from inquiring further, stating, in relevant part:

[Minor Child] has begun hormone therapy - testosterone blocker (Supprelin) via an implant and estrogen via pills (Estradiol).

I don't expect that you will pay for half given your **disapproval of transitioning**.

[Minor Child] started HRT in Aug. [2021] and I waited to tell you to be able to report how it is going so far. I also waited because frankly I am concerned how you will react and potentially act out to our children and me. Friday night's incident of you harassing me [by enquiring about the Minor Child], with [younger son] witnessing some of it, confirms my concerns and that [younger son] will have to resume therapy with Adam when football concludes.

[Exh. "C", p. 14, bolding added]

- 111. WPATH DEFENDANTS are state actors as in addition to being members of WPATH, each is employed by UCSF, undisputedly a California "public trust" under the California Constitution. [Cal. Const. Art. 9, sect. 9(a)].
- 112. Defendants Asaf Orr, Christine Underhill, Nathaniel Bigger, and Daniel Harkins (collectively, "NOMINALLY PRIVATE ACTORS") are each *de facto* State Actors. The U.S. Supreme Court established precedent under which private actors will be held as *de facto* state actors, such that a § 1983 claim will lie against them. *Adickes v. S.H. Kress & Co.* 398 U.S. 144 (1970) ("*Adickes*"), and see also *Smith v. Brookshire Bros.*, 519 F.2d 93 (5th Cir. 1975); *Barrett v. Harwood*, 189 F.3d 297, 304 (2d Cir. 1999). A nominally private actor becomes *a de* facto state actor when "the state has so far insinuated itself into a position of interdependence with the [defendant] that it was a joint participant in the enterprise." *Focus on the Family v. Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1267

(11th Cir. 2003) ("Focus"), citing *Willis v. Univ. Health Servs.*, 993 F.2d 837 (11th Cir. 1993), quoting *National Broad. Co., Inc. ("NBC") v. Communications Workers of Am.*, *AFL-CIO*, 860 F.2d 1022, 1026-27 (11th Cir. 1988)) (other citations omitted). A court will examine whether the government and the acting party are "intertwined in a symbiotic relationship," as well as whether the relationship involves "the specific conduct of which plaintiff complains." *Id.*

- 113. Where a state actor and private citizen have a "meeting of the minds" for similar purposes, a private citizen can become a de facto state actor in which a 42 U.S.C 1983 claim may lie. Cox v. Mariposa Cnty., 2022 U.S. Dist. LEXIS 165502, *12 [Harris accused Cox of rape, the Mariposa Conty District Attorney's Office had possession of Harris' text messages that would exonerate Cox, did not preserve those messages, and returned the phone to Harris giving her the opportunity to destroy the evidence, which she did. Harris was a de facto state actor].
- 114. The WPATH DEFENDANTS and the NOMINALLY PRIVATE ACTORS are intertwined in a symbiotic relationship as they agreed to do so, then proceeded in concert with each other to overcome the hurdle of the NO SURGERY INJUNCTION and Hudacko's opposition to gender-related surgical procedures by implanting Supprelin into a minor that could not consent to such a surgery. Their relationship involves the specific conduct of which Plaintiff complains, i.e. the SCHEME and the TRUE WPATH MISSION as defined above.
- 115. The U.S. Supreme Court has found that under the "joint action" test a private party can be fairly said to be a state actor where a private party is a "willful participant in joint action with the State or its agents." *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 923, 102 S. Ct. 2744, 2746 (1982) ("*Lugar*").
- 116. Where "the State has exercised coercive power or has provided such significant encouragement that the choice must in law be deemed to be that of the State" a private party may be designated a state actor. (*Davison v. Facebook, Inc.*, 370 F. Supp. 3d 6212,

- 1 628 (E.D. Va. 2019)(Citations omitted, and internal quotation marks and alteration omitted).
- The involvement of Orr to provide legal advice to REGENTS, Bigger, Underhill, and Harkins, which he along with REGENTS demonstrates knowledge that Judge Hiramoto's order affected, or could affect the consent needed for the surgical Supprelin implant. Orr states in his Motion to Dismiss that he was an unpaid volunteer and gave "his legal opinion to UCSF that hormone suppressor treatment did not constitute a violation of the custody
 - 118. Upon information and belief, Orr also conferred with Bigger, Harkins and Underhill, using his position of authority, to conspire with them to "evade" REGENT's clear constitutional duty to obtain Hudacko's consent in advance of his son's surgical Supprelin implant.
 - 119. Upon information and belief, Orr and the REGENTS encouraged Bigger, Underhill and Harkins that Underhill's consent was the only authority needed despite the prohibition of surgical procedures in the NO SURGERY ORDER.
 - 120. Harkins is a state actor, or in the alternative, a *de facto* state actor.

order." Dkt. No. 32-1, at 2, 4.

- 121. Harkins was assigned by the family court to act as "minor's counsel" pursuant to Family Code §3151. Neither Hudacko or Underhill made such a request. As a result of Harkins' assignment by the California state judiciary, Harkins' actions are those of the State of California.
- 122. In the alternative, Harkins is a *de facto* state actor: (a) Harkins was aware of the NO SURGERY INJUNCTION; (b) Harkins was aware of Hudacko's opposition to puberty blockers as well as surgical procedures, at the latest on 10/21/2020; (c) Harkins was intimately involved in the joint effort of REGENTS, Orr, Rosenthal, Ehrensaft, Underhill and Bigger to solve the insurance problem and consent issue. [See Exh."G"]; (d) Harkins excluded Hudacko from the discussion and failed to alert Hudacko of the decision unilaterally being made among the Defendants; (e) Harkins had an email exchange with Underhill on May 11, 2021 and call with "counsel." Upon information and belief, that

1 "counsel" either was Orr or Bigger, as Hudacko did not have counsel on or about May 13, 2 2021. [See Exh. "F"] Upon information and belief, the "conference call" included Harkins, 3 and Orr and Bigger and included a discussion and agreement to engage in the SCHEME. 4 123. Both the WPATH DEFENDANTS and the NOMINALLY PRIVATE ACTORS are 5 all willful participants in the plan to commit INVOLUNTARY HUMAN MEDICAL 6 EXPERIMENTATION by performing gender identity related surgery on a minor without 7 Hudacko's consent, and thus in violation of Hudacko's fundamental constitutional rights. 8 124. WPATH DEFENDANTS and NOMINALLY PRIVATE ACTORS are all willful 9 participants in the plan to deceive Underhill into believing that GENDER AFFIRMING 10 CARE is safe and effective so that she would consent on behalf of Minor Child. 11 125. Furthermore, WPATH DEFENDANTS and NOMINALLY PRIVATE ACTORS are 12 all willful participants in the plan to conceal from Underhill and from the public at large the 13 experimental nature of GENDER AFFIRMING CARE in general, and of the Supprelin 14 Implant surgery in particular. 15 126. WPATH DEFENDANTS and NOMINALLY PRIVATE ACTORS are all willful 16 participants in the plan to conceal from Hudacko their intentions to perform the Supprelin 17 Implant, with each of them knowing that it would violate Hudacko's fundamental 18 constitutional rights, as those rights were reiterated in the NO SURGERY INJUNCTION. 19 127. WPATH DEFENDANTS and NOMINALLY PRIVATE ACTORS' concerted 20 conduct in formulating, concealing and executing the SCHEME and in advancing the TRUE 21 WPATH MISSION worked to the mutual benefit of WPATH DEFENDANTS and the 22 NOMINALLY PRIVATE ACTORS. The SCHEME was successful, as WPATH 23 DEFENDANTS were paid a total of at least \$209,820.34. [EXHIBIT "L", p. 71]; and 24 Rosenthal obtained another subject for the EXPERIMENT, thus advancing the goals of the 25 TRUE WPATH MISSION. Plaintiff is informed and believes, and on that basis alleges, that 26 discovery will show that some part of that \$209,820.34 ended up in the hands of each of the 27 WPATH DEFENDANTS and each of the NOMINALLY PRIVATE ACTORS.

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paycheck for "legal services" rendered ostensibly for representing UCSF (Orr), Underhill
(Bigger) and Minor Child (Harkins), but in reality representing and advancing the interests
of the TRUE WPATH MISSION.
130. Therefore, there is sufficient nexus between THE WPATH DEFENDANTS and
NOMINALLY PRIVATE ACTORS so as to find a "joint action" for purposes of 42 U.S.C.
§ 1983.
FIRST CAUSE OF ACTION
42 U.S.C. § 1983
Deprivation of Fundamental Right to Direct a Minor Child's Medical Care
Without Due Process and Conspiracy to Same
(As to Stephen Rosenthal, MD; Janet Yi Man Lee, MD; Diane Ehrensaft, PhD; Asaf Orr
as de facto state actor; Christine Underhill as a de facto state actor, and Daniel Harkins
as de facto state actor)
131. Plaintiff repeats and incorporates by reference the facts alleged above.
132. The Fourteenth Amendment provides, in relevant part, that:
No Stateshalldeprive any person of liberty without due process of law.
[U.S. Constitution, Amend. XIV]
24
EDWARD HUDACKO v STEPHEN ROSENTHAL ET. AL. AMENDED COMPLAINT

133. As the Supreme Court has repeatedly observed, the "'liberty' specially protected by the Due Process Clause includes the right[] ... to direct the ... upbringing of one's children." *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). That right is deeply embedded in "[t]he history and culture of Western civilization." *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972).

134. Upheld in "a long line of cases," *Glucksberg*, 521 U.S. at 720, the rights to custody and the upbringing of one's children are deemed "essential" and "far more precious ... than property rights," *Stanley v. Illinois*, 405 U.S. 645, 651 (1972). See also *Troxel v. Granville*, 530 U.S. 57, 65 (2000) ("*Troxel*") ("The liberty interest at issue in this case—the interest of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court."); *Michael H. v. Gerald D.*, 491 U.S. 110, 123 (1989) (noting "the historic respect—indeed, sanctity would not be too strong a term—traditionally accorded to the relationships that develop within the unitary family"); *Santosky*, 455 U.S. at 753 (The Due Process Clause protects parents' "fundamental liberty interest ... in the care, custody, and management of [their] child[ren]."); *Wallis*, 202 F.3d at 1136 ("Parents and children have a well-elaborated constitutional right to live together without governmental interference," a "liberty interest protected by the Fourteenth Amendment[.]").

135. Regarding the Fourteenth Amendment, and in the context of the fundamental right to parent, U.S. Supreme Court instructs:

The court has long recognized that the amendment's Due Process Clause, like its U.S. Const. amend. V counterpart, guarantees more than fair process. The Clause also includes a substantive component that provides heightened protection against government interference with certain fundamental rights and liberty interests.

[Troxel, supra, 530 U.S. 57 at 60]

136. *Troxel* unambiguously finds the right to parent to be a *fundamental* constitutional right.

- 1 | 137. What is more, that constitutional parental right includes the right to "make ... judgments" about a minor child's medical care. *Parham v. J.R.*, 442 U.S. 584, 603 (1979).

 That's because "[m]ost children, even in adolescence, simply are not able to make sound judgments concerning many decisions, including their need for medical care or treatment." *Id.* And "[s]imply because the decision of a parent is not agreeable to a child or because it involves risks does not automatically transfer the power to make that decision from the parents to some agency or officer of the state." *Id.*
 - 138. After proceedings in the FAMILY LAW CASE, the Family Court stripped Hudacko of *almost* every aspect of his fundamental right to influence the upbringing of the Minor Child. The remaining aspect of Hudacko's 14th Amendment parental rights was his explicit right to prohibit gender identity related surgery on the Minor Child while the Minor Child was still a minor.

- 139. Plaintiff hereby specifically identifies his fundamental constitutional right to make judgments about S.H.'s medical care, influence the upbringing, and care for his son S.H., specifically in the form of the right to prohibit gender identity related surgery, the deprivation of which is at issue here, and subject to a strict scrutiny level of review. *See United States v. Hancock*, 231 F.3d 557, 565 (9th Cir. 2000) (observing that laws burdening a fundamental right are subject to strict scrutiny).
- 140. Under strict scrutiny, the government's challenged actions are "presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests." *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015).
- 141. The WPATH DEFENDANTS are undisputedly state actors. As discussed above, Defendants Orr, Harkins and Bigger (NOMINALLY PRIVATE ACTORS) are *de facto* state actors under the Joint Action test. (together both are "Collective State Actors")
- 142. These collective state actors cannot satisfy strict scrutiny because there was no compelling state interest in deceiving the public and deceiving Underhill to falsely believe that GENDER AFFIRMING CARE is necessary, safe & effective.

- 1 | 143. There was no compelling state interest for concealing the fact that no good evidence 2 | exists for the claim that GENDER AFFIRMING GARE is effective at treating gender 3 | dysphoria.
- 4 | 144. There was no compelling state interest for concealing the fact that GENDER 5 | AFFIRMING CARE greatly increases the risk of all sorts of physical and mental harm.
- 145. 6 The Collective State Actors, the Defendants, each of them, as alleged in the 7 foregoing paragraphs incorporated herein by this reference, acted in concert by meeting 8 with each other, without Plaintiff, via telephone, email and/or in person, discussing, then 9 coming to a meeting of the minds to and, in fact, effecting the Supprelin surgery on 10 Plaintiff's minor son, without Plaintiff's knowledge or consent. They achieved their goal – 11 namely to engage the minor in human experimentation for money. There was no compelling 12 state interest for violating Plaintiff's constitutional right to make judgments about S.H.'s 13 medical care, his upbringing, and care namely to prohibit any gender identity related surgery 14 especially considering that Plaintiff's right was reiterated in the NO SURGERY 15 INJUCTION Court Order.
- 16 146. Defendants each knew that the points in the PLAYBOOK are false, and intended to accomplish the GOALS of the TRUE WPATH MISSION.
 - 147. Defendants each knew that Minor Child was being subjected to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION.
- 20 | 148. Defendants each knew that about the NO SURGERY INJUNCTION.

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- 21 | 149. The consent to GENDER AFFIRMING CARE (including but not limited to consent to Supprelin Implant surgery) that the WPATH DEFENDANTS appeared to obtain from Underhill was no consent at all, because it was fundamentally based on false and fraudulent pretenses i.e. the PLAYBOOK.
 - 150. Defendants each acted under color of law and violated Hudacko's fundamental constitutional right to direct the medical care of his son by accepting money in exchange for advancing the interests of the TRUE WPATH MISSION by performing gender identity related surgery on a minor without obtaining necessary consent.

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27 28 151. Defendants each acted under color of law when they agreed to and committed the overt act of violated Hudacko's fundamental constitutional rights when they accepted money in exchange for subjecting the Minor Child to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION in the form of the Supprelin surgery, while concealing that fact from the public, from Underhill, and from Hudacko.

Therefore, Defendants are individually liable for violation of Hudacko's fundamental 152. parental rights. Since Defendants acted together in a common plan, which plan is herein termed the SCHEME, and which SCHEME is a part of the TRUE WPATH MISSION, Defendants are liable in a conspiracy to violate Hudacko's fundamental parental rights.

SECOND CAUSE OF ACTION

Fraud by Concealment

(Edward Allyn Hudacko v. Stephen Rosenthal, MD; Diane Ehrensaft, PhD; Janet Yi Man Lee, MD; and Asaf Orr)

- 153. Plaintiff repeats and incorporates by reference the facts alleged above.
- All parties to this action were aware of and bound by the NO SURGERY INJUNCTION, which injunction reiterates that Hudacko has a right to prohibit any gender related surgery on Minor Child.
- 155. The WPATH DEFENDANTS are bound by a duty to refrain from committing INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION and to follow the FAMILY LAW Court Order - NO SURGERY INJUCTION.
- 156. As an officer of the Court, Asaf Orr knew that violation of a Court Order is illegal and violation of the Health and Safety Code sections 24170 et seq is illegal and had a duty to follow both the law and the Court order. The WPATH defendants, as medical providers, knew or should have known the same and had a duty to disclose the true dangers of gender affirming care to both parents of S.H. as well as follow the law and court orders.
- Underhill owed Plaintiff a fiduciary duty and the duty of good faith and fair dealing as a former spouse and co-parent.
- 158. Defendants, each of them, intentionally failed to disclose the SCHEME to Hudacko, failed to disclose their economic and research interests, failed to follow the law and a court

order, and by doing so breached their duty to Plaintiff. *Moore v. Regents of University of California*, 51 Cal. 3d 120, 130

- 159. That is, Defendants concealed their plan under which gender identity related surgery was to be performed on the minor child without Hudacko's consent at all, and without proper informed consent from Underhill. The plan included an agreement to conceal the plan from Hudacko until after it was too late. Importantly, the plan included an agreement to conceal from both Hudacko and Underhill the fact that Minor Child was participating in a human medical experiment in violation of the law.
- 160. Defendants actively prevented Hudacko from discovering the SCHEME by ignoring Hudacko's requests both formal and informal for information about medical procedures planned by them on S.H. at UCSF.
- 161. Defendants actively prevented both Hudacko and Underhill from discovering the INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION by failing to disclose that Rosenthal obtains federal funding for experimenting on transgender children, failing to disclose the false and fraudulent nature of statements regarding the WPATH "standard of care" and that proffering that GENDER AFFIRMING CARE is purportedly safe and effective when they knew it is not, and failing to disclose the many life altering known risks of GENDER AFFIRMING CARE, which are many and profound.
- 162. Hudacko did not know that Defendants were planning to perform gender related surgery on the minor child until October 18, 2021, months after surgery was actually performed.
- 22 | 163. Neither Hudacko nor Underhill knew that GENDER AFFIRMING CARE is experimental or dangerous to children.
 - 164. Defendants and each of them knew perfectly well that Hudacko did not and would not approve of gender identity related surgery on the minor child. Defendants and each of them knew perfectly well that neither Hudacko nor Underhill did would approve of subjecting Minor Child to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION.

For this reason, Defendants, collectively and individually, intended to deceive Hudacko and the public at large and thereby breached their duty to disclose.

- 165. Had the SCHEME been disclosed prior to the gender identity related surgery being performed, Hudacko reasonably would have behaved differently. Among other possible actions, Hudacko could and would have brought the SCHEME to the attention of the Family Court, seeking an emergency protective order placing all Defendants on notice that severe consequences sufficient to stop the SCHEME would result from any violation of the NO SURGERY INJUNCTION.
- 166. Defendants' concerted actions in performing the gender identity related surgery in the face of the NO SURGERY INJUNCTION, and in the face of the Health and Safety Code, the Nuremberg Code, and in concealing the SCHEME from Hudacko, and in concealing the EXPERIMENT from Underhill (as a pretext to obtain consent) were undertaken knowingly, intentionally, willfully and with oppression, fraud and/or malice under the meaning of California Civil Code § 3294.
- 167. Hudacko was harmed emotionally, as he suffers severe anguish, fright, horror, nervousness, grief, anxiety, worry, shock, humiliation, and shame, knowing that his son, whom he loves with all of this heart, has been sterilized, and fearing all of the possible negative lifelong detrimental effects, as discussed throughout.
- 168. Hudacko an ordinary, reasonable person is unable to cope with his emotional distress. It negatively affects his work life and his personal life on a daily basis.
- 169. Hudacko was harmed financially as he has expended, and will continue to expend money for treatment of his emotional distress and for attorney's fees to prosecute this action.
- 170. But for the concealment, Hudacko would have been able to stop the gender identity related surgery from going forward, thereby avoiding his injuries. If Underhill had been apprised of the dishonesty at play, it is plausible that Hudacko would have been able to talk sense into her. At minimum, Defendants' concealment was a substantial factor in causing Hudacko's injuries.

Therefore, Defendants are liable for Fraud by Concealment, and a civil conspiracy

THIRD CAUSE OF ACTION

Negligence

Infliction of Emotional Distress

(Edward Allyn Hudacko v. Stephen Rosenthal, MD, Diane Ehrensaft, PhD, Janet Yi Man Lee, MD; Asaf Orr; and Christine Underhill)

- Plaintiff repeats and incorporates by reference the facts alleged above.
- Defendants were each aware of the fact that Hudacko, like any good parent, would be traumatized upon learning that his child had been subjected to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION. Thus, Defendants and each of them owed Hudacko an affirmative duty to refrain from participating in the SCHEME and to refrain from advancing the WPATH TRUE MISSION.
- 174. Defendants, as medical professionals, members of WPATH had a duty to disclose their economic interests and research involving experimentation on children. Moore v. Regents of University of California, 51 Cal. 3d 120, 130
- 175. Defendant Underhill as former spouse to Plaintiff and co-parent owed a fiduciary duty and duty of good faith and fair dealing.
- Defendants further owed Hudacko an affirmative duty to refrain from plotting and 176. planning to willfully violate the NO SURGERY INJUNCTION.
- 177. Defendants further owed Hudacko an affirmative duty to refrain from concealing the SCHEME from Hudacko.
- 178. Defendants and each of them breached their duty to Hudacko subjecting Minor Child to INVOLUNTARY HUMAN MEDICAL EXPERIMENTATION.
- 179. As a direct and proximate result of Defendants' breach of duty, Hudacko was harmed emotionally, as he suffers severe anguish, fright, horror, nervousness, grief, anxiety, worry, shock, humiliation, and shame.

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- 1 | 180. Hudacko an ordinary, reasonable person is unable to cope with his emotional 2 | distress. It negatively affects his work life and his personal life on a daily basis.
 - 181. Hudacko was harmed financially as he has expended, and will continue to expend money for treatment of his emotional distress.
 - 182. Defendants Negligence was a substantial factor in causing Hudacko's emotional distress.
 - 183. Therefore, Defendants are jointly and severally liable for Negligent Infliction of Emotional Distress.

V. PRAYER FOR RELIEF

- Wherefore, Plaintiff prays for relief as follows:
- 11 | 184. **General Damages** for pain and suffering in an amount found reasonable, but not less than \$1,000,000;
 - 185. **Actual Damages** for Plaintiff's medical and other expenses actually and proximately caused by Defendants' conduct, in an amount to be proven at trial, but not less than \$200,000;
 - 186. **Punitive Damages** for intentional torts, to the extent Defendants' conduct is found to constitute fraud, malice or oppression under Cal. Civ. Code § 3294, to punish Defendants, make examples of them, and to deter future such conduct, in an amount sufficient to accomplish the purpose of punitive damages, in light of the net worth of Defendants, such amounts to be proven at trial;
 - 187. **Declaratory Judgments** as stated above;
 - 188. **Costs and Fees** as incurred in prosecuting this action, including reasonable attorney fees as allowed by contract or by statute;
 - 189. **Any Other Relief** the Court may deem appropriate.

VI. DEMAND FOR JURY TRIAL

190. Plaintiff hereby demands a trial by jury on all issues so-triable.

Respectfully submitted on August 30, 2024,

Tracy L Henderson, Esq.
Attorney for Edward Allyn Hudacko

CERTIFICATE OF SERVICE I hereby certify that on this August 30, 2024 I electronically transmitted the attached document to the Clerk's Office using the CM/ECF filing and transmittal Notice of Electronic Filing to all CM/EDF registrants for this case. Dated: August 30, 2024 /s/ Tracy L. Henderson, Esq. By: P.O. Box 221562 Carmel, CA 93922 tlhlaw@protonmail.com

EXHIBIT A

1)19-056+1 12-16-2020 Jam

PRE-TRIAL ORDER FOR LONG CAUSE [ZOOM] TRIALS IN DEPARTMENT 32

Before the long-cause trial of any issue, the parties are ordered to comply with the following requirements. Failure to comply may result in sanctions being imposed.

MY TRIAL DATE:

30 days before the date set for trial:

<u>Discovery</u>: Discovery must be completed 30 days before trial, except that any expert witness may be deposed as late as 10 days before trial.

Expert Witnesses: Unless demanded earlier pursuant to CCP §2034.230, disclose in writing any expert witnesses (including non-retained, percipient witnesses such as a treating physician). The written disclosure shall include a time estimate for direct examination, a summary of the testimony, a summary of the expert's qualifications and a copy of the expert's report, if one has been prepared.

30 DAYS BEFORE:

14 DAYS BEFORE:

7 DAYS BEFORE:

DEC OF DISC's WAIVED?

yes Xno

14 days before the date set for trial:

Serve and file a list of all non-expert witnesses, by name, date of birth if known, a time estimate for direct examination, and relevance to trial.

7 days before the date set for trial:

- [1] <u>Declarations of Disclosure:</u> Unless the requirement is mutual waived, or not required by Family Code § 2106, serve declaration of disclosure on the other party.
- [2] <u>Income & Expense Declaration</u>: Each side must serve on the other party and file with the Court, unless the parties mutually waive this requirement.
- [3] Exhibits: Exhibits are to be pre-marked with exhibit stickers. Serve pre-marked exhibits on the other party. Exhibit stickers must include:
 - [a] Numbers for Petitioner (1,2,3), Letters for Respondent (A,B,C), and

[b] The case number on each sticker.

[c] ANY DOCUMENT LONGER THAN 10 PAGES MUST HAVE ALL PAGES NUMBERED [BATE STAMPED]

[d] Any audio/video recording must be accompanied by a proposed transcript of what is said on the recording. Don't forget to mark the transcript as an exhibit.

[4] Trial briefs: Serve on the other party and file with the Court

<u>Stipulations</u>: Before trial, the parties shall meet and confer and attempt to stipulate to facts, accuracy of transcripts, and admissibility of evidence.

Manner of Service: Any document served on another party 7 days or less before trial must be served by hand delivery, or, if the receiving party has agreed, by email or fax.

Day of trial:

[1] Submit an Exhibit List identifying the pre-marked exhibits (with two columns, labeled "Identified" and Admitted") to the Courtroom Clerk.

[2] Original Exhibits: Place the **original** exhibits in a binder with a copy of the Exhibit List and hand it to the Bailiff when the case is called on the day of trial. **IF** TRIAL IS TO BE VIA ZOOM, PLEASE SUBMIT THE EXHIBITS TO THE COURT CLERK 5 COURT DAYS IN ADVANCE OF TRIAL

BOTH SIDES AGREE
TO EMAIL FOR
SERVICE?

____YES ____NO
___7 days or < only
____FOR ALL TRIAL DOCS

IF TRIAL VIA ZOOM

7 DAYS BEFORE:

[3] <u>Copies</u>: Please supply 3 copies of the exhibits (one each for yourself, opposing counsel AND third copy for use by witnesses). Each party should bring his or her own copy of the opposing party's exhibits as received from the opposing party. IF TRIAL WILL BE IN PERSON PLEASE BRING EXHIBITS ON DAY OF TRIAL.

Version 6/1/2020

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E-MAIL ADDRESS (Optional):				
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PETITIONER/PLAINTIFF: CHRISTINE F	HUDACKO			PNOW E W EDEN
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by Judge (name): JONI HIRAMO			ary Judge	CUDISTINE HUDACKO
On the order to show cause, notice of m	notion or request			(name): CHRISTINE HUDACKO
a. 🔲 Petitioner/plaintiff present	•	Attorney	present (name)	NATHANIEL BIGGER
a. Petitioner/plaintiff present b. Respondent/defendant present	· :	Attorney Attorney	present (name) present (name)	NATHANIEL BIGGER H. NATHAN JAMES
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Page 1 OF ATTACHMENT

This court has jurisdiction to make child custody orders in this case under the Uniform Child Custody Jurisdiction and Enforcement Act (Fam. Code §§ 3400-3465). The responding party was given notice and an opportunity to be heard as provided by the laws of the State of California.

The country of habitual residence of the children is the United States. If you (a party) violate this order, you may be subject to civil or criminal penalties, or both.

All orders not inconsistent with this order remain in full force and effect.

The parents attended Tier 1 confidential mediation on March 5, 2020 and no agreements were reached. The court reviewed the Tier 2 report of the interviews of the parents, the children and of Spencer's therapist dated August 24, 2020.

The court also reviewed the report of Minor's Counsel, Dan Harkins, dated August 14 2020. The court notes that the parties previously stipulated and the court ordered that Sanchez objections shall not apply to the report of minor's counsel. The court also reviewed the confidential document submitted by minor's counsel and ordered that it be sealed and retained in the confidential section of the court's file.

PARENTS: CHRISTINE HUDACKO [MOTHER] v. EDWARD HUDACKO [FATHER]

CHILDREN: SPENCER HUDACKO (DOB 6/10/04) AGE 16
WILL HUDACKO (DOB 6/01/06) AGE 14

WILL HUDACKO (DOB 6/01/06) AGE 14

- 1. **<u>LEGAL CUSTODY of WILL HUDACKO</u>**: the parties agree and the court orders that the parties shall share joint legal custody of **Will Hudacko**.
 - a. In exercising joint legal custody, the parents shall share in the responsibility, confer in good faith, and agree on matters concerning the health, education, and welfare of Will Hudacko. The parents must confer and agree in making decisions on the following matters:
 - i. Enrollment in or leaving a particular private or public school or daycare center.
 - ii. Will Hudacko participating in particular religious activities or institutions.
 - iii. Will Hudacko beginning or ending psychiatric, psychological, or other mental health counseling or therapy.
 - iv. Selecting a doctor, dentist, or other health professional for Will Hudacko (except in emergency situations).

Page 2 OF ATTACHMENT

- v. Will Hudacko participating in organized extracurricular activities.
- vi. Will Hudacko traveling out-of-country.
- b. If a party does not obtain the consent of the party to those items in ¶ 1a (see above), which are granted as court orders:
 - i. He or she may be subject to civil or criminal penalties.
 - ii. The court may change the legal and physical custody of Will Hudacko.
- c. Health-care notification. Each parent shall notify the other parent of the name, address, and telephone number of each health practitioner who examines or treats Will Hudacko; such notification must be made within 24 hours of the commencement of the first such treatment or examination.
- d. Both parents' written consent or court order is required prior to the administration of any prescribed psychotropic medications for Will Hudacko. Upon receipt of written consent or court order, both parents shall administer psychotropic medications are prescribed.
- e. Both parents are required to administer all prescribed non-psychotropic medications for Will Hudacko.
- f. Except for any current court orders intended to protect the address of either parent who is the protected party of a restraining order, each parent shall have access to all medical and school records pertaining to Will Hudacko and shall be permitted to consult with any and all professionals involved with the children. Each parent shall be responsible for contacting the school(s) and medical provider(s) to receive information. Both parents shall have the right to supply information to all providers.
- g. Each parent is authorized to take any and all actions necessary to protect the health, safety, and welfare of Will Hudacko, including but not limited to consent to emergency surgical procedures or treatment. The parent authorizing such emergency treatment shall notify the other parent as soon as possible of the emergency situation and of all procedures or treatment administered to Will Hudacko.
- h. School Notification/Emergency Contact Forms. Except for any current court orders intended to protect the address of either parent who is the protected party of a restraining order, each party will be designated be

Page 3 OF ATTACHMENT

designated on all of Will Hudacko's emergency contact forms as a person to be contacted in the event of an emergency regarding Will Hudacko.

- i. Name. Neither parent shall change the last name of Will Hudacko or have a different name used on Will Hudacko's medical, school, or other records without the written consent of the other parent.
- 2. <u>LEGAL CUSTODY OF SPENCER HUDACKO</u>: Mother shall be the sole temporary legal custodial parent of Spencer Hudacko and may make decisions on her own for Spencer's health, education and welfare without Father's consent.

Except for any current court orders intended to protect the address of either parent who is the protected party of a restraining order, **Father** shall have the right to obtain all otherwise confidential information regarding Spencer Hudacko's health, education and welfare. **Father** can exchange information with the Spencer Hudacko's school, childcare provider(s), doctor(s), dentist, coaches, tutors and therapist(s).

Mother must provide Father with a list of Spencer Hudacko's treating medical (including dental and mental health) professionals, coaches, teachers, and tutors, including name and contact information. Dan Harkins, minor's counsel representing Spencer Hudacko, may assist Father in having the providers contact Father.

Mother is not ordered specifically to provide Father with "updates" on a monthly or weekly basis. Mother may provide such information to Father at her discretion. Father may contact Spencer's doctors, teachers, etc., for information about Spencer. Father does not have a "right" to attend medical appointments for Spencer.

3. PHYSICAL CUSTODY:

- A. Father shall not have visitation with Spencer Hudacko unless it is in a therapeutic setting with Spencer's consent.
- B. Father shall temporarily provide care for Will Hudacko as follows. Every other week with the exchange at Sunday at 7:00 p.m. Father shall have the week beginning August 30, 2020.

Page 4 OF ATTACHMENT

Mother shall provide the **children**'s physical care when they are not otherwise court ordered or mutually agreed between the parents to be in **Father's** physical care.

- 4. **Minor's Counsel**. The parties agree and the court orders that Mr. Harkins shall continue to serve as minor's counsel for both children. Costs of minor's counsel shall be paid for by Father 70% and by Mother 30%.
- 5. **Reunification Therapy**. The parties agree and the court orders that the court's previous order that the parties participate in Reunification Therapy is rescinded. The parties are not required to participate in Reunification Therapy at this time.
- 6. Individual Therapy for the children.

The parties shall cooperate to ensure that Will continues to participate in individual therapy with Adam Moss at least twice a month, or with a different frequency, as recommended by the therapist.

Petitioner shall ensure that Spencer continues to participate in individual therapy with Lee Townsend at least twice a month, or with a different frequency, as recommended by the therapist.

7. Services for Spencer Hudacko.

- a. Spencer shall be permitted to pursue the services provided by UCSF as to Spencer's gender identity, and shall be permitted to commence hormone therapy, if recommended by UCSF.
- b. Spencer will not be permitted to undergo any gender identity related surgery until they are 18 years of age, absent a written agreement by both parties, Christine Hudacko and Edward Hudacko, or an order of the court.
- c. Mother shall ensure that Spencer receives an annual physical examination by their medical physician. This has already occurred during the summer of 2020.
- d. Spencer shall not be required to undergo a neuropsychological evaluation, unless recommended by UCSF.
- e. Spencer shall not participate in any assessment by Dr. Craig Childress absent a written agreement by both parties, Christine Hudacko and Edward Hudacko, or a showing of a substantial change of circumstances and an order of the court.

Page 5 OF ATTACHMENT

- e. Spencer shall not participate in any assessment by Dr. Kenneth Zucker absent a written agreement by both parties, Christine Hudacko and Edward Hudacko, or a showing of a substantial change of circumstances and an order of the court.
- f. Spencer shall not participate in any assessment or services offered by Dr. Childress, Dr. Devita Singh, Dr. Zucker, Dorcy Pruter or Dr. Warshak absent a written agreement by both parties, Christine Hudacko and Edward Hudacko, or a showing of a substantial change of circumstances and an order of the court.
- 8. **Spencer's 529 account.** The issue of whether Edward Hudacko shall be ordered to replace, from community funds, the \$20,000 he removed from Spencer's 529 account and used to pay school tuition for both children shall be reserved for long cause trial. The court admonishes the parties that money from the 529 accounts should not be removed without the agreement of both parties or a court order.
- 9. **Exclusive use and possession of the marital residence at 3030 Clinton Avenue**, **Richmond**. The parties agree and the court orders that exclusive use and possession of the marital residence shall be temporarily awarded to Respondent. The parties agree and the court orders that Respondent is admonished of his fiduciary duty to maintain the community asset and pay its obligations until otherwise agreed by the parties in writing or further order of the court.
- 10. Petitioner may retrieve personal belongings from the marital residence with at least 24 hours' notice to the Respondent.
- 11. The court declines to make an order regarding 2001 Chevy Camaro at this time.
- 12. Respondent's request to order Petitioner to "obtain full-time employment immediately" is reserved for a long cause trial. Respondent's request to impute Respondent with \$200,000 income a year is reserved for a long cause trial. Jurisdiction is reserved to the date of Petitioner's filing.
- 13. Respondent is admonished that he is not to drop Petitioner nor the children from any insurance coverage or policy. Coverage is to be maintained it was on December 31, 2019.

Page 6 OF ATTACHMENT

- 14. Respondent's request for sanctions shall be reserved for long cause trial.
- 15. Respondent is admonished to keep minor's counsel fees paid in a timely manner.
- 16. **Holiday schedule for Will**. To be reserved for long cause trial. The court attaches, as a courtesy, a sample template for the parties to consider.
- 17. The parties shall return to Dept. 32 (via Zoom use the same Personal Meeting Id, 633 639 9336 and the same password, 2qyWb4) on December 16, 2020 from 9:30 a.m. to 4:30 p.m. for long cause trial on the issues specified above.

Date: August 26, 2020

Joni Hiramoto

Judge of the Superior Court, Dept. 32

AUGUST 26, 2020

Page 7 OF ATTACHMENT

Sample Holiday Schedule for Will Hudacko (Not ordered by the court. The parties shall attempt to meet and confer prior to trial.)

HOLIDAY	TIME	EVEN YEARS	ODD YEARS	
Easter Sunday	9:00am until 8:00pm	Mother	Father	
Mother's Day	9:00am until 8:00pm	Mother	Mother	
Father's Day	9:00am until 8:00pm	Father	Father	
July 4	9:00am on 7/4 until 9:00am on 7/5	Mother	Father	
Thanksgiving	9:00am until 8:00pm	Father	Mother	
Winter Break	9:00am until 8:00pm Father Mother Winter break shall be split in half each year. Mother shall have the half with Christmas Day in it during even years. Father shall have the half with Christmas Day in it during odd years.			
Child's Birthday	To be celebrated on each par	rent's custodial t	me.	
Parents' Respective Birthdays	To be celebrated on each par			

EXHIBIT B

4/10/23, 6:11 PM Mail - Ted Hudacko - Outlook

RE: Spencer update incl. both children's school progress reports

Christine Hudacko <christinehudacko@yahoo.com>

Tue 9/29/2020 1:08 PM

To: Ted Hudacko <thudacko@rocketsciencesystems.com>

UCSF has the court order per their request. Their policy pertains to joint legal custody.

Sent from Mail for Windows 10

From: Ted Hudacko

Sent: Tuesday, September 29, 2020 9:23 AM

To: Christine Hudacko

Subject: Re: Spencer update incl. both children's school progress reports

Removing lawyers to reduce costs.

Re: UCSF, Dr. Ehrensaft, the director of mental health, finally returned my call made in July. She and I spoke briefly. She said UCSF policy is inclusion of both parents in meetings. I do not have the relevant zoom information.

From: Christine Hudacko <christinehudacko@yahoo.com>

Sent: Tuesday, September 29, 2020 9:12 AM

To: Ted Hudacko

Cc: dshark1@pacbell.net; Nathaniel Bigger; Nate James

Subject: Spencer update incl. both children's school progress reports

Hi Ted, Attached are both children's progress reports for the first term at St Mary's, in case you didn't yet see. They are both doing really well. St. Mary's remains very rigorous in their learning despite online learning environment, so their achievements are commendable.

RE our move, which you were notified about when I signed the lease earlier in the month, we will be moving into the condo later this week and expect our first night there to be Sat.

RE Spencer's health appointments, reminder that Spencer has an orthodontist check-up Tues., 10/6, and UCSF zoom meeting Tues., 10/13. Spencer continues to see Lee week on-week off.

Thanks, Chris

Sent from Mail for Windows 10

EXHIBIT C

Case 3:23-cv-05316-SI Document 90 Filed 08/30/24 Page 49 of 139

From: Christine Hudacko christinehudacko@yahoo.com

Subject: update on Spencer's health **Date:** October 18, 2021 at 7:47 PM

To: Ted Hudacko thudacko@rocketsciencesystems.com

Cc: Nathaniel Bigger nate_bigger@yahoo.com, Daniel S. Harkins dshark1@pacbell.net

Ted, Spencer has begun hormone therapy - testosterone blocker (Supprelin) via an implant and estrogen via pills (Estradiol). Spencer is doing well and happy to finally begin the process. I believe that Spencer has been very supported by UCSF and therapists over the past 12 months in determining this was the right step for them. Spencer continues to see Dr. Barrow to be supported. Insurance has paid for the vast majority of implant procedure and I sent UCSF a check for the balance (\$2035.64). I don't expect that you will pay for half given your disapproval of transitioning.

Spencer started HRT in Aug. and I waited to tell you to be able to report how it is going so far. I also waited because frankly I am concerned how you will react and potentially act out to our children and me. Friday night's incident of you harassing me, with Will witnessing some of it, confirms my concerns and that Will will have to resume therapy with Adam when football concludes.

-Chris

Sent from Mail for Windows

EXHIBIT D

AA-17905'01*110552-MO-21237-65157-ACUS 42SN



nited HealthCare Services, Inc. ICHARDSON/SPRGFLD SRVC CNTR O BOX 30555 ALT LAKE CITY. UT 84120 OFFF ALT LAKE CITY, UT 84130-0555 hone: 1-866-348-1286

August 25, 2021

for all your claim and benefit information. Have more questions about your claim?

Claim Detail for SPENCER HUDACKO

Provider: J LEE

Claim Number: CW3504121601

Patient Account Numbers

\$72 3	\$0.00	\$72.38	\$0.00	\$0.00	\$651,41	\$723.79	\$21.21	3/45,00		
\$72.3	\$0.00	\$72.38	\$0.00	\$0.00	\$651.41	\$723.79	\$21.21	\$745.00	01	ZGEXY
Amount You Ov/e**	Non-Covered	Coinsurance	Сорау	Deductible	Your Plan Paid	Amount Allowed	Plan Discounts	Amount Billed	pe of Service Notes*	pe of Ser
	wider	ponsibility to Provider	Your Itemized Respons	You					:	.

Date(s) of Service

Claim Total: 38/04/2021 SUR

**This total does not reflect any payments / copays you made at the time of service or purchase
Please wait for a provider bill before making a payment.

\$72.38

\$0.00

\$72.38

M - THE PLAN DISCOUNT SHOWN IS YOUR SAVINGS FOR USING A NETWORK PROVIDER. THE AMOUNT YOU OWE MAY INCLUDE YOUR COPAY OINSURANCE, DEDUCTIBLE, PLUS ANY AMOUNT DUE IF YOU'VE REACHED YOUR BENEFIT LIMIT ON A COVERED SERVICE. notices about the deadline extensions and how they may apply to you. lease note that appeal deadlines have been extended until further notice due to COVID-19. You should consult

vith your employer and visit the US Department of Labor website at dol.gov for more information and additional

overed members of your family. lecause your family deductible has been satisfied, your remaining individual deductible has been adjusted to \$0. The coinsurance period of your plan has begun for all

lenial, we will complete our review not later than 30 days after we receive your request for review utlanta, GA 30374-0816. The request for your review must be made within 180 days from the date you receive this statement. If you request a review of your claim review of this benefit determination may be requested by submitting your appeal to us in writing at the following address: UnitedHealthcare Appeals, P.O. Box 740816

your plan is governed by ERISA, you may have the right to file a civil action under ERISA if all required reviews of your claim have been completed

o the appeal address referenced above 'ou or your authorized representative, such as a family member or physician, may appeal the decision by submitting comments, documents or other relevant information

ou may request copies (free of charge) of information relevant to your claim by contacting us at the above address

STD-EOB

000000298349429

Use this EOB statement as a reference or retain as needed

Page 2 of 5

EXHIBIT E

Name: Gemma Hudacko | DOB: 6/10/2004 | MRN: 45479935 | PCP: Eileen G. Aicardi, MD

Letter Details (Gemma)

UCSF Health 1825 4TH ST FL 6

UCSF Pediatric Endocrine

SAN FRANCISCO CA 94158-2515

Phone: 415-353-7337 | Fax: 415-476-8214

February 17, 2021

Spencer Hudacko (AKA: Gemma) [MRN: 45479935] Patient:

6/10/2004 Date of

Birth:

2/17/2021 Date of

Visit:

UCSF Benioff Children's Hospital Child and Adolescent Gender Clinic (CAGC)

PUBERTAL BLOCKERS

Parent or Guardian Consent

Before considering a medication for your child to put puberty "on hold", there are several things you need to know. There are possible advantages, disadvantages and risks with pubertal blockers. We have listed them here for you. It's important that you understand all of this information before your child begins the medication.

Please read the following carefully and ask us any questions. We want you to be very comfortable and sure of what pubertal blockers offer your child. We have a simpler version that we ask recommend you and your child read together.

After your questions or concerns are addressed and you have decided to proceed with the pubertal blocker medication for your child, both you will need to sign this information and consent form. You and your child will also need to sign the consent form that you read with your child.

What are the different medications that can help to stop the physical changes of puberty?

The main way that the physical changes of puberty can be put on hold is by blocking the

signal from the brain to the organs that make the hormones of puberty. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testes.

The medications are called Pubertal Blockers or GnRH agonists. Examples include leuprolide acetate injections (1, 3, 4, 6 month), triptorelin injections (6 months), or histrelin subcutaneous implants (1-2 year). This medication is effective for both males and females. They can be started just after the early physical changes of puberty, or anytime after puberty has started.

For transgender girls, there are alternative medicines that can block the effect of testosterone. The most common medication of this type is an oral tablet called **spironolactone.** There is a separate consent form for this medication. Spironolactone is not as effective at blocking puberty in transgender girls, but it is much less expensive.

Every medication has risks, benefits, and side effects that are important to understand before starting. It is also important to know how they work.

Medications for Blocking Puberty

I understand that:

Puberty Blockers are used to help temporarily suspend or block the physical changes of puberty.

Puberty blockers usually suppress puberty after one month of starting the medication.

This medication is not specifically made for the purpose of blocking puberty (they are not FDA approved for this purpose). In transgender youth, pediatric endocrinologists (children's doctors who work with hormones and puberty), recommend these medications if the physical changes of puberty need to be postponed. They have been in use for this purpose for many years.

The medication is not permanent. If my child stops the puberty blocker, my child's body will restart the changes of puberty at the developmental stage they were at when they started the hormone blocker after about 6-12 months.

While taking these medications, my child's body will not be making the hormones of puberty (testosterone or estrogen).

While taking these medicines, my child may be avoiding the unhappiness and trauma of unwanted puberty, giving your child the opportunity to develop in their affirmed gender, with a better fit between body and mind.

Puberty blockers may avoid the need for surgeries and other treatments (i.e. mastectomies for transmen, tracheal shaving or electrolysis for transwomen) that would be required to try to reverse the effects of puberty.

Taking puberty blockers may also improve safety and integration into society when

transgender girls are adults. This is because transgender women who underwent male puberty are often unable to 'pass' as female because of irreversible changes that male puberty causes.

It is recommended that my child and family participate in therapy with a therapist experienced in gender issues while my child is taking the hormone blocker.

Risks of Puberty Blockers

I understand that:

The side effects and safety of puberty blockers are not completely understood. There may be long-term risks that are not yet known.

My child will likely not have a pubertal growth spurt while on pubertal blockers alone. In transgender boys, delaying the onset of puberty may actually make them slightly taller if the growth plates are open.

There may be a delay of typical adolescent cognitive or brain development while on these medicines. This will resume when not taking the blocker.

The normal increase of **bone mineral density** that occurs during puberty is likely to be reduced while on pubertal blockers. Bone mineral density will continue to increase at a prepubertal rate while on puberty blockers. We expect that bone mineral density will be normal compared to peers either when pubertal blockers are discontinued, or when pubertal blockers are combined with cross-sex hormones (estrogen/testosterone). However, the long term effects of puberty blockers that are used alone are not completely understood.

Blocking puberty at an early stage will likely limit the potential for **fertility**. Options for fertility preservation have been discussed with my provider.

Puberty blockers will stop the development of puberty in my child and other people may notice. As my child becomes older, this may become more apparent.

Some transgender people have experienced harassment and discrimination. I can get resources that will support my child and family. I may have to advocate for my child to participate safely and free from harassment in schools and other activities.

I can ask my child's provider and therapist for help advocating for my child.

Prevention of Medical Complications

I understand that:

My child should take puberty blocking medication as prescribed. I will tell my child's health care provider if my child has any problems or side effects or is unhappy with the medication.

My child needs periodic clinic visits to make sure that my child is responding appropriately

to the puberty blocker.

Puberty blockers are used off label for blocking puberty in patients with gender dysphoria. I know this means it is not approved by the Food and Drug Administration for this specific use. I know that the medication that is recommended for my child is based on the judgment and experience of our health care provider and is supported by the Society of Pediatric Endocrinology and World Professional Association of Transgender Health (WPATH).

My child can choose to stop taking these medications at any time. If my child decides to do that, I will stop the medications with the help of my health care provider.

My signatures below confirm that:

- My child's health care provider has talked with me about:
 - the benefits and risks of puberty blockers for my child.
 - the possible or likely consequences of using puberty blockers.
 - potential alternative treatments.
- The information in this form includes the known effects and risks. There may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my child's health care provider.
- All of my questions have been answered to my satisfaction.
- My child is in agreement with this treatment and the signature of my child on the Child's Puberty Blocker consent form attests to this agreement.
- My signature attests to your consent for your child to begin the Puberty Blocker.

My signature below confirms that:

- 1. I understand the potential benefits and risks of puberty blockers (GnRH agonists), the possible or likely consequences of puberty blocker therapy, and potential alternative treatment options.
- 2. I understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- 3. I have discussed puberty blockers with my provider, received sufficient information to make a decision, and all my questions are answered.
- 4. I agree to the monitoring plan of care, including <u>regular medical visits</u> with a CAGC provider (every 3-6 months) and <u>blood tests</u> (every 6-12 months), and imaging such as bone density scan or bone age x ray (every 1-2 years). Failure to follow the monitoring plan of care may result in discontinuation of the puberty blocker prescription.

I do want my child to begin receiving drinn agonist (puberty blocker) me	fulcation.
--	------------

Parent or Guardian signature	Date	
Parent or Guardian signature	Date	
Patient signature	Date	
Prescribing clinician signature	Date	
Gemma Hudacko, 2/17/2021 11:05 AM	Page 2 of	4

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EXHIBIT F

LAW OFFICE OF DANIEL S. HARKINS PO BOX 1677 DANVILLE, CA 94526-6677 APRIL 30, 2022
PLEASE PAY \$1,184.49 BY
05/23/2022
THANK YOU

PLEASE SEND PAYMENT TO:

EDWARD HUDACKO
THUDACKO@ROCKETSCI

LAW OFFICE OF DANIEL S. HARKINS PO BOX 1677 DANVILLE, CA 94526-6677

CLIENT #2140 HUDACKO E MINOR'S COUNSEL CLIENT #2140 HUDACKO E MINOR'S COUNSEL	INVOIC	E #029119
PLEASE DETACH AND RETURN WITH YOUR PAYMENT OF \$1,164.49	INVOIC	E#029119
CLIENT #2140 HUDACKO E MINOR'S COUNSEL		
HUDACKO MINOR'S COUNSEL		20 . 20 .
PROFESSIONAL SERVICES SINCE THE LAST STATEMENT	HOURS	FEES \$1,592.50
06/29/20 DSH E-MAIL TO COUNSEL, REVIEW ORDERS	4.90	\$227.50
07/02/20 DSH READ PLEADINGS PROVIDED	0.70	\$68.25
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TOWNSEND	0.21	\$68.25
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07/24/20 DSH ZOOM MEETING WITH WILL	0.70	\$227.50
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.08/11/20 DSH CALL WITH SPENCER	1.30	\$422.50
:08/11/20 DSH MEETING WITH RESPONDENT AND COUNSEL	0.21	\$68.25
08/12/20 DSH E-MAILS FROM MR. JAMES; REPLY	1.75	\$568.75
08/12/20 DSH DRAFT MINORS REPORT	0.35	\$113.75
08/13/20 DSH CALL WITH DR. EHPSENSAEFT- SECOND CALL	0.49	\$159.25
08/14/20 DSH REVISE REPORT, PREPARE CONF. DOCUMENT	0.28	\$91.00
08/17/20 DSH PREPARE SUPPLEMENT TO MCR	0.14	\$45.50
08/17/20 DSH READ REPLY DECLARATION FROM PETITIONER	0.28	\$91.00:
08/18/20 DSH CALL WITH WILL HUDACKO	0.28	\$91.00
08/20/20 DSH READ RESPONDENT'S REPLY DECLARATION	0.52	\$169.00
08/20/20 DSH CALL WITH SPENCER	1.40	\$455.00
08/25/20 DSH SUPERIOR COURT APPEARANCE	0.49	\$159.25
08/25/20 DSH PREPARE FOR HEARING	-	04/00/00

PAGE 1 OF 3

2140

HUDACKO E MINOR'S COUNSEL

04/30/22

		OR'S COUNSEL		0.21	\$68.25
		CALL FROM LEE TOWNSEND		0.21	\$91.00
		E-MAIL FROM NATE J, REPLY, E-MAIL TO NATE F		0.26	\$45.50
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		E-MAIL FROM MR. JAMES (2), REPLY		0.35	\$113.7
		E-MAILS FROM NATE JAMES, REPLY		0.35	\$113.7
		PREPARE EX PARTE REQUEST FOR ORDER		1.05	\$341.2
		PREPARE RESPONSE TO RESPONDENTS EX PARTE		0.21	\$68.2
		READ TED'S LETTER TO UCSF		0.21	\$68.2
1/05/20	DSH	PREPARE RESPONSE TO REQUEST FOR ORDER		0.24	\$78.0
1/06/20	DSH	E-MAIL TO PARTIES AND COUNSEL		0.14	\$45.5
1/09/20	DSH	READ RESPONDENT'S REPLY, BRIEF, EXPERT DISCLOSURE		0.56	\$182.0
1/12/20	DSH	PREPARE FOR HEARING		0.35	\$113.7
1/13/20	DSH	SUPERIOR COURT APPEARANCE		1.05	\$341.2
1/30/20	DSH	DRAFT NOTICE- NON EXPERT WITNESS		0.14	\$45.5
		DRAFT HEARING BRIEF		0.36	\$117.0
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		PREPARE FOR HEARING		0.35	\$113.7
		SUPERIOR COURT APPEARANCE		3.85	\$1,251.2
		DRAFT RESPONSE TO 2/18/21 REQUEST FOR ORDER		0.42	\$136.5
		READ PETITIONER'S RESPONSE		0.28	\$91.0
		E-MAILS REGARDING DROPING HEARING		0.21	\$68.2
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		CALL WITH MR. TOWNSEND		0.35	\$113.7
		E-MAIL FROM MR. BIGGER, CALL WITH MR. TRIANO		0.21	\$68.2
		E-MAIL FROM MOTHER, CALL WITH COUNSEL		0.21	\$68.2
		READ TEXT EXCHANGE BETWEEN SPENCER AND DAD		0.14	\$45.
		E-MAIL TO CLIENTS		0.07	\$22.
		CONFERENCE CALL WITH COUNSEL		0.35	\$113.
				0.35	\$113.
		TELEPHONE CALL WITH CLIENT SPENCER		0.05	\$16.
		E-MAIL FROM MS. HUDACKO		0.28	\$91.
07/22/21		RESEARCH SPENCERS ISSUE		0.20	\$29.
		CALL WITH COUNSEL		0.15	\$48.
		COURT APPEARANCE E-MAIL FROM MR. HUDACKO, CALL FROM MR. HUDACKO		0.21	\$68.
11/11/21				0.21	\$68.
11/29/21		REVIEW HOSPITAL BILL		0.35	\$113.
		TELEPHONE CALL WITH CLIENT-SPENCER		0.28	\$91.
		CALL FROM COUNSEL READ T.R.O		0.21	\$68.
		E-MAIL FROM COUNSEL;MULTIPLE		0.21	\$68.
		READ RESPONDENTS RFO/OST		1.05	\$341.
		PREPARE RESPONSE TO RFO/OST		0.35	\$113.
		LETTER TO COUNSEL			\$113. \$45.
		E-MAIL EXCHANGE WITH COUNSEL		0.14	ъ45. \$45.
		CALL FROM MS. CAMPBELL		0.14	
		E-MAIL EXCHANGE, E-MAIL CLIENT		0.21	\$68.
03/30/22	DSH	CALL WITH GEMMA	TOTAL.	0.21	\$68.
			TOTAL:	39.99	\$12,996.
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DSH	D.	ANIEL S. HARKINS, ESQ. \$325.0	0	2.55	\$828.

PAGE 2 OF 3

2140

HUDACKO E MINOR'S COUNSEL

04/30/22

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EXHIBITS TO COMPLAINT p. 26

HUDACKO E MINOR'S COUNSEL

2140

PAGE 3 OF 3

EXHIBIT G

UCSF MyChart - Visit Summary 1/30/22, 8:32 PM

Name: Gemma Hudacko | DOB: 6/10/2004 | MRN: 45479935 | PCP: Eileen G. Aicardi, MD

A Note to Patients: Symptoms are concisely summarized to inform treatment recommendations. For reasons of privacy and brevity, this note does not attempt to capture all experiences that were discussed.

Progress Notes

Stephen M Rosenthal at 6/8/2021 4:00 PM

Subjective:

Subjective

Chief Complaint
Patient presents with

Follow-up

I performed this evaluation using real-time telehealth tools, including a live video Zoom connection between my location and the patient's location. Prior to initiating, the patient consented to perform this evaluation using telehealth tools.

HPI 16 y.o. 11 m.o. transgender female.

Checklist complete for starting E2 (prefers estrace) and histrelin.

Pt's mother in contact with Asaf Orr. Mother and pt have separate attorneys who are navigating complex family situation; in particular insurance issues, as pt is currently using father's insurance and father is not supportive of pt's gender care. Mother has complete medical custody

Patient's allergies, medications, past medical, surgical, family and social histories were reviewed and updated as appropriate.

Review of Systems

Objective:

Objective

There were no vitals taken for this visit.

Physical Exam

HENT:

Head: Normocephalic.

Neurological:

https://ucsfmychart.ucsfmedicalcenter.org/UCSFMyChart/inside.asp...wxzkozfWJCPtybV7YbnqiCMUyHU8BU0S-2FqfvNidCQj8-3D&printmode=true

UCSF MyChart - Visit Summary 1/30/22, 8:32 PM

Mental Status: He is alert.

Psychiatric:

Mood and Affect: Mood normal.

Lab Review:

not applicable

Assessment:

Assessment

16 y.o. 11 m.o. transgender female.

Checklist complete for transition.

Awaiting resolution of insurance issues and family issues as noted above.

Plan:

Plan

Mother is working with her attorney, Gemma's attorney and Asaf Orr, JD--everyone is working together to achieve resolution in near future.

Mother will keep J. Cohen, LCSW, informed of situation. follow up to be arranged.

I spent a total of 40 minutes on this patient's care on the day of their visit excluding time spent related to any billed procedures. This time includes time spent with the patient as well as time spent documenting in the medical record, reviewing patient's records and tests, obtaining history, placing orders, communicating with other healthcare professionals, counseling the patient, family, or caregiver, and/or care coordination for the diagnoses above.

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EXHIBIT H

Child Custody's Gender Gauntlet | City Journal



EYE ON THE NEWS

Child Custody's Gender Gauntlet

Transgender ideology has already achieved a powerful hold on our court system—and parents and children are paying the price.

Abigail Shrier

February 7, 2022

Before she decided to strip him of all custody over his son, Drew*—before determining that he would have no say in whether Drew began medical gender transition—California Superior Court Judge Joni Hiramoto asked Ted Hudacko this: "If your son [Drew] were medically psychotic and believed himself to be the Queen of England, would you love him?"

"Of course I would," the senior software engineer at Apple replied, according to the court transcript. "I'd also try to get him help."

"I understand that qualifier," Judge Hiramoto replied. "But if it were—if you were told by [Drew's] psychiatrist, psychologist that [Drew] was very fragile and that confronting him—or, I'm sorry, confronting *them* with the idea that they are not the Queen of England is very harmful to their mental health, could you go along and say, 'OK, [Drew], you are the Queen of England and I love you; you are my child and I want you to do great and please continue to see your psychologist.' Could you do that?"

"Yes," Hudacko said. "That sounds like part of a process that might take some time, sure."

"What process?" Judge Hiramoto said. "What is the thing that might take some time? Accepting the idea that [Drew] occupies an identity that you believe is not true?"

"The identity you just mentioned to me was the Queen of England," Ted began. "I can tell him and I can affirm that to him, to reassuring him situationally; but objectively, he is not the Queen of England and that won't change, and even the therapist in that case would know that."

Child Custody's Gender Gauntlet | City Journal

The then-54-year-old father of two teenage minor sons (Drew is the elder) felt that he was walking into a trap. For Ted, precision is not merely a requirement for his job but almost a constitutional necessity. His recall of every fact, date, and filing of the complicated court proceedings involving him and his ex-wife is astoundingly accurate—the sort of feat you might expect from a brilliant lawyer, not a distraught father battling the legal system alone for his son.

But at this point in the child-custody hearings, Ted couldn't understand what the judge wanted from him. His soon-to-be-ex-wife, Christine, then an executive at the investment firm BlackRock, had already agreed to shared custody of their younger son; no one—not even this judge—seemed to believe that he was anything like an unfit father.

Ted isn't a particularly devout Episcopalian, and he describes his politics as libertarian. He's athletic, health-conscious, and takes a keen interest in his sons' talents. He coached their baseball teams and researched conservatory programs for Drew, already an accomplished pianist. Just one year earlier, Ted had been one-half of a Bay Area power couple with high-status careers and precocious kids. Now, he was one-half of a contentious divorce, presided over by a judge who was referring to Drew as "they" and pressing Ted to accept that his 16-year-old son was actually a girl.

"And do you think that being transgender is a sin?" Judge Hiramoto asked, according to the transcript.

"No, of course I don't think it's a sin."

"So you don't think that it's a sin. But you probably think that [Drew], if they are truly transgender, you would prefer that [Drew] not be transgender because in our society transgender people are the subject of a lot of discrimination. Would you agree with that?"

"I agree that transgender people suffer some discrimination and prejudice. I agree with that," he said.

"I'm sort of going off the parallel experiences that I've read about or heard in family court or in family law classes for judges where gay children come out to their parents," the judge said. "And sometimes it is difficult for the parents because they believe that the identity of being gay or lesbian, in their religion, is a sin. And then some people don't feel that it's a sin, but they say—they take a different angle, and they say, I just would prefer my child not to be gay or lesbian because they suffer so much discrimination in our society.

"So I'm sort of asking these parallel questions to see what is your—what I see in the papers is that you think that [Drew] is not truly transgender and that they are merely confused and—"

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"He might be transgender," Ted said. "He might be."

"Okay. So if [Drew] might be transgender, it's just to say they might."

Ted realized his error and corrected himself: he had used the "he" pronoun because he remained deeply skeptical that the boy he'd coached in little league—the son he'd once seen crushing on a cute girl in his fifth-grade class—was actually a young woman.

"They might be," Ted said. "[Drew]—they might be. Might be. We don't know."

While trying to keep an open mind about Drew's gender, Ted was adamant to the judge that he did not want Drew to begin medical transition. In the 312 days since he had last seen his boy, Ted had done a lot of research on medical transition and gender dysphoria. He begged the court to consider research that suggested puberty blockers could impair cognition and diminish bone density. He knew that Drew, if administered puberty blockers along with estrogen, would be at high risk of permanent infertility. He wasn't even sure that his son had gender dysphoria. He wanted to see his son—and he wanted this bullet train to slow down.

"It sounds to me that you would prefer that [Drew], when all is said and done, is just going through a phase. Is that a fair assessment?"

Ted evaded the question. Did he prefer that his son avoid a medically risky regimen that would render him permanently infertile and make him a lifetime medical patient? Wouldn't anyone?

In the three years I've spent writing about families with transgender-identifying minors, the story of Ted Hudacko stood out as a case study of how gender ideology has infiltrated family law. It also frames the unintended consequences of medical professionals' fudging science, rewriting medical definitions, and tolerating shoddy research to placate activists. At each stage, doctors may have thought: Where was the harm? And so, as a consequence, judges now decide the fate of children and their families based on phony, medically unsubstantiated metaphysics, as if it were factual that all adolescents have an immutable, ineffable "gender identity," knowable only to the adolescents themselves.

On June 24, 2020, following her discussion with Ted about the Queen of England hypothetical, Judge Joni Hiramoto granted Christine sole legal custody of Drew on a temporary basis and approved the shared legal and physical custody arrangement of their younger son. She assured Ted that her order was not yet permanent. Judge Hiramoto had decided to order the appointment of a minor's counsel to investigate how the boys were faring before making any permanent decisions. She already had the perfect person in mind. "I actually know of one who was previously appointed by the court, by a

 $file: ///Users/thudacko/Desktop/Bar_Complaint_Dan_Harkins/Exhibit-H~Child~Custody's~Gender~Gauntlet~_City~Journal.mht$

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different judge, on a case involving children that were allegedly transgender," she said. That minor's counsel was attorney Daniel Harkins.

Ted didn't know it yet, but the appointment of Harkins would place the final nail in the coffin of his parental rights. Within just a few months, the court would definitively end Ted's parental relationship. He would have no right to see Drew, no right to talk to him, no right to demand that Drew attend therapy with him, and absolutely no right to stop a medical transition already planned by the Child and Adolescent Gender Center of UCSF Benioff Children's Hospital.

And finally, the court also felt that Ted had no right to know that Judge Hiramoto had a transgender child of her own, whose gender transition she had publicly supported. No one disclosed this information to the parties.

If first spoke to Ted in May 2021, after Judge Hiramoto—following the recommendation of minor's counsel—had stripped him of all custody of Drew. Ted was leaning heavily on support groups just to get himself through the day. He compared himself to the morose Edward Norton character from the movie *Fight Club*, who attends multiple support groups to relieve his depression and insomnia. "I'm in six support groups," Ted said, laughing a little at himself.

Ted estimated that he had spent only 75 minutes total with Drew in the previous 12 months. His wounds were raw. Part of him wanted to blast his story across America, but he also worried that he might lose any remaining chance to see his son again if he did so. He had dismissed his attorney, who had failed to restore any of Ted's rights, notwithstanding \$25,000 in legal fees. For four months, Ted had been representing himself in court, filing motion after motion, attempting to terminate the appointment of the minor's counsel (denied), pleading the court for more access to his son (also denied). The man I spoke to was distraught, half in shock, like someone arriving home from work to find his house being bulldozed.

The whole notion that Drew might be transgender still seemed bizarre to Ted—a fantasy told about someone else, bearing no connection to him. Even his divorce still seemed more like a nightmare than waking life. Sure, Christine had been distant in their marriage for some time, Ted told me, but that was easy to explain: for more than a year, she had been distracted by tragedy. In 2018, Christine's sister had been stabbed 23 times at her workplace by her own estranged husband, who had recently been discharged from an inpatient mental-health facility. Christine spent the next year shuttling from the Bay Area to upstate New York to aid her sister's recovery and provide evidence to strengthen the district attorney's attempted murder prosecution. For the sentencing phase of the criminal trial—in June and July 2019—Christine stayed on the East Coast with both boys.

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Ted was then fully preoccupied with a grueling six-week project for Apple. He hadn't slept well in weeks, he says. On a Saturday in August 2019, shortly after returning from upstate New York with the boys, Christine walked into Ted's home office and announced both that she was leaving and that their son Drew was transgender. By his own admission, Ted became angry. He believed Christine must have talked Drew into this during their weeks together in upstate New York. Ted says he begged to have this conversation after he had gotten some sleep. But Christine walked out, taking the kids to stay with her at a neighbor's house.

"Saturday, when she left, I was under the impression, mistaken impression, that, you know, she simply temporarily left," he said. "You know, maybe going out to get some fresh air or to just get, you know, give us some space or maybe even have gone to see a movie. I just went upstairs. I didn't get up till the following morning."

Court documents reveal Ted's struggles with the court-appointed minor's counsel, Daniel Harkins. No part of his tragedy is more Kafkaesque.

Harkins met with both boys, interviewed Drew's therapist and both parents, and conducted two 90-minute interviews with Diane Ehrensaft of the UCSF Benioff Child and Adolescent Gender Clinic. Harkins also did some research on Ken Zucker, the Toronto-based psychologist and gender dysphoria specialist whom Ted preferred. Harkins never spoke with Zucker.

Zucker is arguably the world's leading expert on gender dysphoria. He oversaw the writing of the entry of the condition for the DSM-5, the most recent *Diagnostic and Statistical Manual of Mental Disorders*. He also helped write the most recent final "Standards of Care" guidelines for the World Professional Association of Transgender Health. (New final standards are forthcoming.)

Zucker is a practitioner of "watchful waiting," a method of exploratory therapy that considers gender as only one component of what may be causing a child's distress. Watchful waiting, to its proponents, is the more prudent approach to treating gender-dysphoric minors, as it recognizes that over 70 percent of kids with gender dysphoria typically outgrow it. In 2015, Zucker was fired from his clinic following an activist-led campaign to purge Canada of psychologists who opposed immediate "affirmation" and transitioning for kids experiencing gender dysphoria. (The hospital that fired Zucker and shuttered his clinic later publicly apologized to him and paid him nearly \$550,000, plus legal fees, for having smeared him and misrepresented his work.) Put simply, Zucker's approach directly contradicts the "affirmative" approach now in vogue, which places gender-dysphoric minors in the driver's seat of their own diagnosis and treatment. Harkins's preferred expert, Diane Ehrensaft, is a leading advocate of the affirmation-only approach, and Harkins appears to have accepted her views as dogma.

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By contrast, Harkins dismissed Zucker as a crank. "His views are controversial, and I have been informed are discredited in the psychological community," Harkins wrote. As for Zucker's approach—an attempt to encourage a child to grow more comfortable in his body by using psychotherapy to explore all his sources of distress—Harkins expressed concern that "his approach is a step away from what is referred to as conversion therapy, if not in fact conversion therapy." That Zucker oversaw the writing of the very clinical definition of "gender dysphoria" that Harkins cites as authoritative in his report, Harkins does not mention.

Ted also supplied the court with an article by journalist Jesse Singal that explained Zucker's work and told the story of the activist mob that claimed Zucker's job. Harkins appears to have been unmoved: "Mr. Singal is clear that he is troubled by transgenders. He refers to Zucker's work frequently in his articles. He has been criticized as trans-phobic. It is difficult to see why a journalist's opinion should be given much weight," Harkins wrote. Instead, Harkins seems to have uncritically adopted the view of a gender-medical provider who has staked her career on the existence of ineffable genders—the incongruence of which with biological sex can only be rectified through a combination of affirmation, hormones, and surgery.

Ted lost his cool during their interview, according to Harkins: "During the interview, with his attorney present, Father became very upset and stated that 5 years from now when [Drew] realizes he is [sic] mutilated himself, he will have to be there to pick up the pieces—not minor's counsel."

Ted's outburst might strike many parents as reasonable. Who was this guy, freshly on the scene, to decide whether Ted could ever see his kid again and what pieces of Drew's anatomy should be surgically removed? But Harkins read between the lines and discerned in Ted the wrong view of gender identity—namely, that it might not be immutable: "This is indicative of father's view of [Drew's] gender identity. It also gives us an insight as to his view in general about transgender people. He simply does not see this as a viable alternative. He is very frustrated that he has not been able to express all these ideas directly to [Drew]."

Based on the lengthy minor's counsel report, Harkins gave Ted's parenting a failing grade: "Father has not been accepting of [Drew's] status as transgender. He has been quite clear that he does not accept that [Drew] is in fact transgender."

It's possible that Harkins has never met a father so "wrong" in all his views as Ted Hudacko. "Father has requested that a parental alienation assessment be performed by Dr. Craig Childress. First, it needs to be pointed out that parental alienation is not a proper or accepted term. The appropriate term is alignment. This means the child has aligned themselves with one parent and against the other."

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As for Ted's proposal that a psychological expert in "parental alienation" compel Drew at least to talk to his father, Harkins can only tut-tut: "It is unfortunate but it appears that father is willing to use coercion in an attempt to force [Drew] to have a relationship with him instead of trying to accept [Drew], offer them unconditional love and listen to what he wants."

Even Ted's withdrawal from a 529 education-savings account to pay for Drew's prep school tuition becomes, in Harkins's report, further proof that Ted was "willing to use punitive measures to [sic] for [Drew] to communicate with him on his terms." In Harkins's book, Ted could simply not stop failing. "He is also not looking at [Drew] as an independent person." Drew was 16 at the time.

Harkins seems to have been offended by Ted's suspicion that Christine had influenced their son's new identity or turned Drew against him. Harkins wrote in his report: Ted "questioned whether [Drew] wrote communications to him because of the sophistication of the language," according to Harkins's report. "[Drew] confirmed he wrote those communications. He had some help on the grammar but the thoughts are all his." Harkins might have asked: Grammar help from whom? And was it help of a "not 'there' but 'they're'" variety, or more like, "Move over so I can type"?

Either way, Harkins crowned Christine the winner of the parenting contest and Ted the sore, mixed-up loser. "[Drew] is an independent very bright young person. Facing gender identity issues is difficult. I don't think anyone who has not gone through this process can truly understand how difficult it must be the feel [sic] that you are on [sic] the wrong body and you are willing to go through painful surgery to correct the problem. [Drew]'s mother has given him unconditional love. She reports when she asked father if he could give [Drew] unconditional love and he stated that he did not know what that was."

Summarizing matters as a gender-ideology-addled King Solomon might have, Harkins wrote: "These parents have a choice, they can either continue to believe that they should be in total control of their child's life or they can come to an understanding that those days are past and they need to work with their children and give their children some independence and the ability to make some of their own decisions." With the help of gender doctors who will profit handsomely from the procedures, of course.

Harkins's judgment was swift and ironclad: mom should retain full legal custody on a permanent basis and provide Ted updates, at her discretion, regarding matters that affect Drew's health, education, and welfare. Drew would commence hormone therapy, as directed by USCF. Judge Hiramoto made all this official. The only right that Ted seems to have retained is the power to prevent Drew from undergoing "any gender identity related surgery" before he turns 18, absent agreement of both parties.

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In October 2021, Ted was stunned by a \$209,820.34 charge on his insurance statement. When he wrote to Christine, she confirmed that a puberty-blocking implant had been inserted in Drew's arm months earlier and that Drew had begun a course of cross-sex hormones. The combination—if not soon stopped—would likely sterilize Drew. No one had asked Ted's permission for the procedure or even informed Ted of what had been done.

Ted responded to this news with a flurry of e-mails to Christine's attorney. He told Christine's lawyer that the medical procedure was in violation of a court order, and Christine was risking being held in contempt of court. A day later, Christine's lawyer filed a request for a Domestic Violence Restraining Order against Ted, alleging that he had spoken to his ex-wife "menacingly" at their younger son's football games. Ted was served with the temporary restraining order; California law now required him to relinquish all his firearms within 24 hours or potentially face felony charges. He quickly complied.

"It's like being a Rodeo clown or being a professional wrestler," Ted said to me recently, over the phone. "It's like, 'OK, now let's watch Ted get body-slammed. Now watch Joni Hiramoto put him in a headlock.' Now, for my next trick!"

Overwrought and perhaps a touch reckless, Ted joined the Apple Slack channel devoted to "trans kid parenting" and shared his outrage and concern about his son's medical transition and the risks involved. The other members chastised him and reported Ted to "Employee Relations," known everywhere else as "HR." Ted now worries for his job.

As for Judge Hiramoto's potential conflicts of interest, a check of social media reveals the following: On October 1, 2019, on a post of her biologically male child dressed in earrings and makeup, Judge Hiramoto comments: "Proud to be your mom." In May 2020, one month before Ted and Christine Hudacko appeared in court, Judge Hiramoto's son celebrated on Instagram his one-year anniversary coming out as a transgender female. On July 3, 2020—after Judge Hiramoto had entered her first provisional order granting Christine full custody, her transfeminine son posted on Instagram: "This is my first time wearing a bikini." Judge Hiramoto commented: "Beautiful!!"

On February 7, 2021, in another post of her transfeminine child in eye makeup and nail polish, holding up a sea urchin, Judge Hiramoto commented: "That mussel linguine was absolutely delicious! Thank you my darling daughter!!"

On February 9, 2021: "Love the colors and make up!!" And on February 20, 2021, on a post of her adult biological son made up in makeup, lashes and jewelry, with hashtags "#transisbeauatiful" and "#girlslikeus" and "#transvisibility," Judge Hiramoto writes "Sweet!" followed by clapping hands, heart-eyes, and fire emojis. (Judge Hiramoto posted no comments on the several photos in which her kid appears in bondage gear.)

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On her own Facebook page, on June 27, 2015, Judge Hiramoto reposted her picture with the Pride flag transposed over it. And in November 20, 2020, in response to California congressman Mark Takano's post in honor of "Transgender Day of Remembrance," Judge Hiramoto wrote: "Thank you for speaking up for those who face some of the harshest prejudice in our society." (I reached out to Judge Hiramoto, minor's counsel Daniel Harkins, and Christine Hudacko for comment; none of them responded to my e-mails.)

Whether one believes that Hiramoto's social media posts constitute admirable or appropriate parenting is irrelevant to whether any of these created a judicial duty to recuse or a duty to disclose. Without mentioning Judge Hiramoto's name, I consulted two judicial-ethics experts to determine a judge's specific ethical duty under the circumstances. Both experts agreed that while the duty to recuse is hard to establish, the duty to disclose is much broader. "The general rule of thumb with disclosure is that a judge should disclose to the parties anything that the parties would be likely to find relevant to the question of whether or not they should be seeking to recuse the judge," said Richard Flamm, author of the legal treatise *Judicial Disqualification: Recusal and Disqualification of Judges*. I asked him whether, in a custody case in which parents were fighting over whether to transition a minor son, the judge's having a transgender son of her own was something the parties were "likely to find relevant."

"Yeah, I mean, don't you?" Flamm said. "I think most people would think anything is relevant if it's on the same subject matter. So, I gave the example before of a judge who's been an accident victim presiding over a case involving a car accident—should disclose it. A judge who's had a child who was molested, if she's presiding over a case in which one of the parties is accused of molesting somebody's else child, she'd probably disclose that because the parties would find it relevant."

Judge Hiramoto may have had an ethical duty to disclose these facts to the parties. But the more I delved into the case, the more I realized that gender ideology has already achieved a powerful hold on our court system. It's possible that almost any family court judge, with or without a family conflict of interest, could have reached the same conclusions.

At a February 2017 conference of the United States division of the World Professional Association for Transgender Health (USPATH), an attendant asked two of the gender doctors—University of Southern California pediatrician Johanna Olson-Kennedy and Brown University professor of pediatrics Michelle Forcier—whether there was a way legally to compel parents to medically transition their children. "Even if you get a court order, the most protective factor for a good outcome is parental support. So it's not my first line to go to the court to get [a pediatric patient] what they need. But it is my second line and I will do it."

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"There's no precedent" for legally compelling parents, Forcier agreed. "But you can again work with the child protection team for medical neglect. Work with one parent, at least to get things started. And again, you can do some education."

In fact, Forcier added, "We did education with judges in Rhode Island. We spent half a day with family court judges, telling them this is what gender and transgender is."

The efforts of gender activists to educate family law practitioners have borne fruit. In another family court case in Arizona, parents lost custody of their troubled 15-year-old daughter when they refused to agree that she was, in fact, a boy. I spoke to the family lawyer involved in that case, Vernadette Broyles, who managed to obtain from the judge the court-wide "training" sessions she had received on transgender youth. The list, which I obtained, included four separate presentations by activists during the previous two years, in addition to lunch meetings hosted by the "LGBTQ Court-Involved Youth Committee." There is no indication that any of this judicial "training" included hearing from a single de-transitioner—that is, one of a fast-growing movement of young people who already regret their hasty medical transitions—nor from any of the parents who have watched their teens' lives made worse by a sudden gender swap, nor a single psychologist or psychiatrist who maintains skepticism about quick adolescent medical transition as a remedy.

"The problem is, when it's a court-wide training, even if you file a motion to recuse that particular judge, you have no guarantee that you'll be able to get in front of *any* judge that will give you impartial justice," Broyles said.

Judge Hiramoto referred twice in the transcript to the things she had learned in "judicial college" and "family law classes for judges." One thing she learned, it seems, was to refer to all adolescents whose gender identity is at issue as "they/them"—whether or not the gender identity was in dispute. Another thing Hiramoto learned, according to the transcript, was that gender, like sexual orientation, is immutable. Several times she pressed Ted, in several ways, on whether he could accept Drew if it turned out that Drew was "truly transgender."

This is gender ideology—the belief, not backed by any meaningful empirical evidence, that we all have an ineffable gender identity, knowable only to us. This identity has no observable markers, and it is immutable (until the moment we change our minds and reveal ourselves as "gender fluid," of course). It is promoted by virtually every practitioner of "gender-affirming care," it is unfalsifiable, and its hold on our legal system is gaining ground.

After years of lobbying by gender activists, the International Classification of Diseases (ICD), Tenth Revision, which went into effect in January of this year, eliminated the term "gender dysphoria." This standard international textbook of disease renames the condition "gender incongruence," and

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reclassifies it under "sexual health." The psychological symptom—"distress"—no longer appears; according to the most authoritative diagnostic text used by doctors the world over, a once-mental condition is now just a physical one. One might forgive courts for assuming, then, that a physical problem must have a physical solution.

Courts are adopting this view and seeing a child who has a feeling of gender dysphoria as no different from one born with a cleft palate. From this perspective, the only relevant question in a custody dispute involving a transgender-identified minor is: When will you allow him to get the necessary surgery to fix his body? Once a court swallows gender ideology, in other words, judges will believe that the only thing left for a loving parent to do, after an adolescent announces a trans identity, is shuttle him to the doctors who will alter his body and contribute clapping-hands emojis to the photos he posts on Instagram.

As for the doctors and mental-health providers opposing the dogmatic insistences of gender ideology masquerading as science, only a handful are willing to write and fight under their own names: Will Malone, Julia Mason, Patrick Lappert, Paul Hruz, Dr. Paul McHugh, Dr. Stephen B. Levine. And, yes, Ken Zucker. The rest work anonymously, through new organizations that have not yet managed to loosen gender ideology's grip on the courts.

In January 2021, Judge Hiramoto transferred from Family Court of Contra Costa to the Criminal Division. For a year, Judge Wendy Coats presided over the Hudackos' ongoing proceedings. Last Friday, Ted and Christine appeared before their new judge, Benjamin Reyes II. At issue: the temporary restraining order against Ted.

According to several witnesses, Judge Reyes commenced proceedings by stating his pronouns.

* The name has been changed for this article.

Abigail Shrier is a writer living in Los Angeles and the author of Irreversible Damage: The Transgender Craze Seducing Our Daughters.

EXHIBIT I

UCSF MyChart - Visit Summary 1/30/22, 8:11 PM

Name: Gemma Hudacko | DOB: 6/10/2004 | MRN: 45479935 | PCP: Eileen G. Aicardi, MD

A Note to Patients: Symptoms are concisely summarized to inform treatment recommendations. For reasons of privacy and brevity, this note does not attempt to capture all experiences that were discussed.

Progress Notes

Dominique B at 8/4/2021 3:30 PM

Mom with pt. Pt calm, cooperative, asking appropriate questions. VSS. Tolerated procedure well. Both educated on after care. Verbalized understanding.

PROCEDURE CONSENT: THE FOLLOWING WAS DISCUSSED WITH THE CAREGIVER AND PATIENT:

- 1. Provider discussed the medication treatment, including the benefits and risks.
- 2. Procedure summary:
 - A. Patient preparation
 - B. Local anesthesia
 - C. Procedure
 - D. Aftercare
- 3. Potential Risks:
 - A. Infection
 - B. Allergic reaction
 - C. Pain
 - D. Bleeding
 - E. Extrusion
- 4. In the case of an accidental provider needle stick: patient consents to STI testing.

Patient Instructions

Janet Yi Man Lee at 8/4/2021 3:30 PM

Start taking your estrace 2mg/day.

Patient Education:

The histrelin subcutaneous implant was inserted today. Due for removal/replacement by 08/04/2023.

Follow post insertion care instructions below.

Return: schedule follow-up visit in 2 months.

UCSF MyChart - Visit Summary 1/30/22, 8:11 PM

Please repeat the blood work at your preferred lab 1-2 weeks before the followup visit.

1. What is histrelin acetate (Supprelin LA or Vantas implants)? Supprelin or Vantas are gonadotropin releasing hormone (GnRH) agonists. It suppresses luteinizing hormone and follicle stimulating hormone (LH/FSH) and gonadal sex steroids estrogen and testosterone. As a result, puberty is suppressed. However, puberty will resume if the medication is discontinued.

The implant is 3.5 cm long and 3 mm wide.

- **2. Transient worsening of symptoms of puberty** or onset of new symptoms may occur initially. However, within **4 weeks** of histrelin therapy, complete suppression of gonadal steroids occurs and manifestations of puberty decrease.
- 3. <u>Post Insertion Care</u>: refrain from getting the inserted arm wet for 24 hours and from strenuous exertion of the inserted arm for 7 days after implant insertion to allow the incision to fully close (avoid lifting > 25 lb or contact sports until healed). The bandage can be removed after 24 hours. You can take a shower at this point, but avoid submersing the site in water (bath or swimming) until healed. Do not remove the surgical strips; rather, the strips should be allowed to fall off on their own after several days. Once the incision has fully healed, you can resume full activities.

Pain Control Post Procedure: apply ice pack for 10 minutes immediately post procedure. You can take over the counter pain medications such as acetaminophen or ibuprofen as needed for pain. Please see your visit summary medication list for dose and frequency of pain medications.

- **4. Common Adverse Reactions**: bruising, soreness, pain, tingling, itching, swelling at the insertion site. They usually go away without treatment by 2 weeks (typically sooner).
- **5. Uncommon Adverse Reactions:** report to your provider any severe pain, bleeding, redness, or swelling in and around the implant site. Rarely, the implant can be expelled from the body through the original incision site. The site should be checked by the provider 1-2 weeks after the insertion. Serious and life-threatening reactions have happened with GnRH medicines, but these are very rare. Call 911 or go to the nearest emergency room if you have trouble breathing, severe pain, or severe rash.
- **6. Monitoring GnRH agonist therapy:** your provider will monitor LH/FSH/E2/T one month after the implant is placed and every 3-6 months. A DXA scan for bone mineral density will be done yearly if you are not taking estrogen or testosterone. The implant is FDA approved for 12 months of therapy. However, it will last up to two years in many people. Follow up with your provider regarding the appropriate time to remove/replace your implant.

UCSF MyChart - Visit Summary 1/30/22, 8:11 PM

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EXHIBIT J

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use
SUPPRELIN® LA safely and effectively. See full prescribing
information for SUPPRELIN LA.

SUPPRELIN LA (histrelin acetate) subcutaneous implant Initial U.S. Approval: 1991
-----RECENT MAJOR CHANGES------

Warnings and Precautions (5.5)

puberty (CPP) (1).

04/2022

SUPPRELIN LA is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of children with central precocious

----DOSAGE AND ADMINISTRATION-----

The recommended dose of SUPPRELIN LA is one implant every 12 months. The implant is inserted subcutaneously in the inner aspect of the upper arm and provides continuous release of histrelin for 12 months of hormonal therapy (2).

----DOSAGE FORMS AND STRENGTHS-----

SUPPRELIN LA is available as a 50 mg histrelin acetate subcutaneous implant which delivers approximately 65 mcg histrelin acetate per day over 12 months (3).

-----CONTRAINDICATIONS-----

- History of hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analogs (4).
- Pregnancy (4).

-----WARNINGS AND PRECAUTIONS-----

 Initial Agnostic Action: Initial transient increases of estradiol and/or testosterone may cause a temporary worsening of symptoms (5.1).

- Implant Breakage: Have been observed during implant removal.
 Monitor luteinizing hormone, follicle stimulating hormone or testosterone for suppression of CPP (5.2, 5.6)
- Psychiatric Events: Have been reported in patients taking GnRH agonists. Events include emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms. (5.3)
- Convulsions: Have been observed in patients receiving GnRH
 agonists with or without a history of seizures, epilepsy,
 cerebrovascular disorders, central nervous system anomalies or
 tumors, and in patients on concomitant medications that have been
 associated with convulsions. (5.4)
- Pseudotumor Cerebri (Idiopathic Intracranial Hypertension): Have been reported in pediatric patients receiving GnRH agonists.
 Monitor patients for headache, papilledema, and blurred vision. (5.5)

-----ADVERSE REACTIONS-----

- The most common adverse reaction is implant site reaction (51.1%), including complications related to the insertion or removal of the implant (6).
- Adverse events related to suppression of endogenous sex steroid secretion may occur (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Endo Pharmaceuticals Solutions Inc. at 1-800-462-3636 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

-----USE IN SPECIFIC POPULATIONS-----

Use of SUPPRELIN LA in children less than 2 years of age is not recommended (8.4).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 04/2022

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SUPPRELIN LA (histrelin acetate) subcutaneous implant is indicated for the treatment of children with central precocious puberty (CPP).

Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment.

Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dose

The recommended dose of SUPPRELIN LA is one implant every 12 months. Each implant contains 50 mg histrelin acetate. The implant is inserted subcutaneously in the inner aspect of the upper arm and provides continuous release of histrelin acetate (65 mcg/day) for 12 months of hormonal therapy. SUPPRELIN LA should be removed after 12 months of therapy (the implant has been designed to allow for a few additional weeks of histrelin acetate release, in order to allow flexibility of medical appointments). At the time an implant is removed, another implant may be inserted to continue therapy. Discontinuation of SUPPRELIN LA should be considered at the discretion of the physician and at the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males).

2.2 Recommended Procedure for Implant Insertion and Removal

This procedure section is intended to provide guidance for the insertion and removal of SUPPRELIN LA. The actual procedure used, however, is at the discretion of the qualified healthcare provider performing the procedure.

Insertion of a new implant can proceed using the following **Suggested Insertion Procedure**. If a previous SUPPRELIN LA implant must first be removed, please see the **Suggested Removal Procedure** instructions below.

Suggested Insertion Procedure

The supplies necessary to insert the implant, including the Insertion Tool and local anesthetic, are provided in a separate Implantation Kit that is shipped along with the implant. Please note that the implant should be kept refrigerated (2-8°C) in its sealed vial, pouch, and carton, until needed for the procedure. Once removed from refrigeration, the vial containing the implant (still in its unopened pouch and carton) may remain at room temperature for up to 7 days, if necessary, before being used. If not used in that time, the packaged implant may again be properly refrigerated until the expiration date on the carton.

NOTE: The Implantation Kit is to be stored at room temperature and should *not* be refrigerated.

Insertion of the SUPPRELIN LA implant is a surgical procedure. Sterile gloves and aseptic technique must be used to minimize any chance of infection.

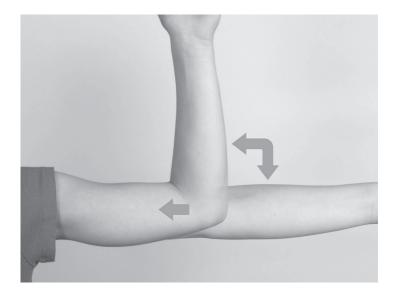
Setting up the Sterile Field

Using proper aseptic technique, the sterilized components of the Implantation Kit needed for the insertion procedure, including the Insertion Tool, are to be carefully dispensed from their packaging onto the Sterile Field drape (nonfenestrated) provided. NOTE THAT THE KIT BOX AND ALL PACKAGING ARE NOT STERILE and should be kept off of the Sterile Field drape. DO NOT PLACE THE VIAL OF LOCAL ANESTHETIC OR THE VIAL CONTAINING THE IMPLANT ONTO THE DRAPE as the exterior surface of these vials is not sterile.

The implant vial should not be opened until just before the time of insertion. Open the vial by removing the metal band and carefully pour the sterile contents (implant and sterile saline) onto the Sterile Field drape. The implant can then be handled with sterile gloves or with the sterile mosquito clamp provided. **AVOID bending or pinching the implant.**

Preparing the Patient and the Insertion Site

The patient should be on his/her back, ideally with the arm least used (e.g., left arm for a right-handed person) positioned, either bent or extended, so that the physician has ready access to the inner aspect of the upper arm. Propping the arm with pillows may help the patient more easily hold the position. The suggested optimum site for subcutaneous insertion is approximately half-way between the shoulder and the elbow, in line with the crease between the biceps and triceps muscles.



Antiseptic

Swab the insertion area with topical antiseptic, then overlay with the *fenestrated* Sterile Field drape provided, so that the opening is over the insertion site (for clarity of illustration, the following images do not show the drape).



Anesthetic

The method of anesthesia utilized (i.e., local, conscious sedation, general) is at the discretion of the healthcare provider.

If local anesthesia is selected: a vial of sterile local anesthetic (note that the exterior of the vial is not sterile) has been provided along with a sterile hypodermic needle for injection. After determining the absence of known allergies to the anesthetic agent, inject anesthetic into the subcutaneous tissue, starting at the planned incision site, then infiltrating along the intended subcutaneous insertion path, up to the length of the implant (a little more than one inch). Local anesthesia may also be supplemented by the use of distraction techniques.



The following sections describe the suggested procedure for insertion of the implant using the Insertion Tool provided. The method of insertion used, however, is at the discretion of the healthcare provider performing the procedure.

Loading the Insertion Tool

The sterile Insertion Tool is comprised of a fixed handle attached to a retractable, bevel-tipped cannula, into the chamber of which the implant is to be placed for subcutaneous insertion. The cannula can be extended and retracted. The fully extended cannula contains a fixed piston upon which the implant, once inserted, rests. During the final step of the insertion procedure, the cannula will be retracted into the handle using the slide mechanism (green button), thereby exposing and leaving the implant to remain in the subcutaneous tissue.

When first grasping the sterile Insertion Tool, confirm that the cannula is fully extended. Verify this by inspecting the position of the green retraction button. The button should be locked in position all the way forward, towards the cannula, farthest from the handle.



The implant can be picked up using sterile gloves or with the sterile mosquito clamp provided. Avoid bending or pinching the implant. Note that the implant may come out of its vial slightly curved and/or partially flattened after refrigerated storage. To help make the implant more symmetrical prior to loading into the Tool, you can roll the implant a few times (while wearing a sterile glove) between the fingers and thumb.

Insert the implant into the cannula of the Insertion Tool manually or using the mosquito clamp. When inserting the implant into the cannula, DO NOT FORCE the implant. If resistance is felt, the implant should be removed and manually manipulated or rolled as needed, and re-inserted into the cannula.





When fully inserted, the implant rests inside the cannula so that just the tip of the implant is visible at the beveled end of the cannula.

Making the Incision

Using the sterile scalpel provided, make an incision transverse to the long axis of the arm, and of a size adequate to allow the bore of the cannula to be inserted into the subcutaneous tissue. Be sure that the incision is positioned so that there is sufficient length of upper arm available to fit the implant easily within the intended insertion space.



Inserting the Implant

It is suggested that insertion may be easier if a "pocket" for the implant is first created by blunt dissection through the incision, subcutaneously along the path of the anesthetic, using the cannula of the loaded Insertion Tool, or using a sterile hemostatic clamp or equivalent surgical tool.

Be sure to VISIBLY RAISE THE SKIN (known as tenting) at all times during the pocket-making and insertion procedures to ensure correct subcutaneous placement ("just under the skin") of the implant. Note that the cannula of the Insertion Tool, or whatever tool is being used to create the pocket, SHOULD NOT ENTER MUSCLE TISSUE. Deep insertion of the implant will not affect the performance of SUPPRELIN LA, but may cause difficulty in the later removal of the implant.

If using the cannula of the loaded Insertion Tool to create the pocket, carefully insert the tip of the cannula into the incision and advance through the subcutaneous tissue, while visibly raising the skin along the length of the cannula up to, but no farther than, the inscribed black line on the cannula. DO NOT DEPRESS THE GREEN RETRACTION BUTTON ON THE TOOL WHILE INSERTING OR ADVANCING THE TOOL INTO THE INCISION.

Pull the Tool back, almost to the beveled tip of the cannula, and advance the Tool forward again, so that the cannula reenters the pocket completely, but no farther than the inscribed black line. Be sure to keep the insertion path just immediately subcutaneous.

If another tool was used to create the pocket, now insert the loaded cannula of the Insertion Tool containing the implant through the incision, up to the inscribed black line.



Hold the Insertion Tool in place with the base against the patient's arm (if possible) as you carefully move your thumb to the green retraction button. Depress the button to release the locking mechanism, then slide the button back toward the handle until it stops, all the while holding the body of the Insertion Tool in place.



Retracting the button causes the cannula to withdraw from the incision, leaving the implant in the subcutaneous tissue. DO NOT FURTHER ADVANCE THE CANNULA ONCE THE RETRACTION PROCESS HAS STARTED. Likewise, do not withdraw the Insertion Tool until the button is fully retracted or the implant may be pulled partially out of the incision. Once the retraction is complete, the Tool can be fully withdrawn.

NOTE: It may be helpful during the process of retraction and withdrawal of the cannula to apply pressure to the skin over the implant, to help ensure that the implant remains in the subcutaneous pocket.

If there is a need to re-start the process at any time during the insertion procedure, withdraw the Insertion Tool, carefully extract the implant from the cannula and reset the retraction button on the Tool to its forward-most position. Examine the implant before reloading the implant into the Insertion Tool, and start again.

Placement of the implant should be confirmed by palpation. Note that the tip of a properly-placed implant may not be visible through the incision.

After implantation, briefly cover the site with a sterile gauze pad and apply pressure to ensure hemostasis.

Closing the Incision

To close the incision, you can use the absorbable sutures and/or the sterile adhesive surgical strips provided. To improve adhesion of the strips, you can apply benzoin tincture antiseptic (provided) to the skin, and let it dry, before applying the adhesive strips.



Once closed, cover the incision site with sterile gauze pads and secure the dressing with the bandage provided.

Please provide the patient's parent or guardian with a Patient Information Leaflet, which includes information about the implant and instructions on proper care of the insertion site.

Suggested Removal Procedure

SUPPRELIN LA should be removed after 12 months of therapy. Most of the supplies necessary to remove the implant, including the local anesthetic and the sterile mosquito clamp, are provided in the Implantation Kit that is shipped along with a new SUPPRELIN LA implant. Note that the Implantation Kit is to be stored at room temperature and must *not* be refrigerated. See the **Suggested Insertion Procedure** above for further instructions.

Removal of the SUPPRELIN LA implant is a surgical procedure. Sterile gloves and aseptic technique must be used to minimize any chance of infection.

Setting up the Sterile Field

Using proper aseptic technique, the sterilized components of the Implantation Kit needed for the implant removal procedure are to be carefully dispensed from their packaging out onto the Sterile Field drape (non-fenestrated) provided. NOTE THAT THE KIT BOX AND ALL PACKAGING ARE NOT STERILE and should be kept off of the Sterile Field drape. DO NOT PLACE THE VIAL OF LOCAL ANESTHETIC ONTO THE DRAPE as the exterior surface of the vial is not sterile.

Preparing the Patient and the Site

The patient should be on his/her back, with the arm containing the implant positioned, either bent or extended, so that the physician has ready access to the inner aspect of the upper arm. Propping the arm with pillows may help the patient more easily hold the position.

The implant to be removed should first be located by palpating the inner aspect of the upper arm, near the incision from the prior year.



Generally, the previous implant is readily palpated. In the event the implant is difficult to locate, ultrasound may be used. If ultrasound fails to locate the implant, other imaging techniques such as CT or MRI may be used to locate it (plain films are not recommended as **the implant is not radiopaque**).

Antiseptic

Swab the area above and around the previous implant with topical antiseptic. Overlay the area with the *fenestrated* Sterile Field drape provided, so that the hole is over the previous insertion site (for clarity of illustration, the following images do not show the drape).



Anesthetic

The method of anesthesia utilized (i.e., local, conscious sedation, general) is at the discretion of the healthcare provider.

<u>If local anesthesia is selected</u>: a vial of sterile local anesthetic (note that the <u>exterior of the vial is not sterile</u>) has been provided along with a sterile hypodermic needle for injection. After determining the absence of known allergies to the anesthetic agent, inject anesthetic into the subcutaneous tissue at and around the site of the intended incision (the site of the previous implant). Local anesthesia may also be supplemented by the use of distraction techniques.



Making the Incision and Removing the Implant

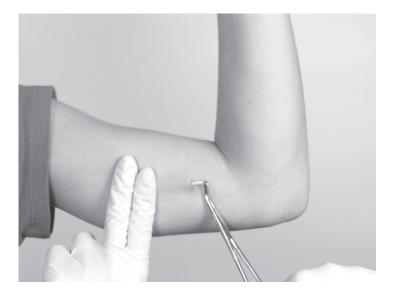
Using the sterile scalpel provided, make an incision of a size adequate to allow the implant to be easily removed and, if a new implant will be inserted, large enough for the bore of the cannula of the Insertion Tool provided.



Generally, the tip of the implant will be visible through the incision, possibly covered by a pseudocapsule of tissue. In order to facilitate the removal of the implant, it may be necessary to palpate the head of the implant through the incision using your smallest finger, especially if the head of the implant is not readily visible. In addition, you may need to push down on the distal end of the implant and "massage it forward" towards the incision.

Carefully nick the pseudocapsule to reveal the polymer tip of the implant. It may be beneficial to insert the sterile mosquito clamp provided into the hole created in the pseudocapsule and expand by opening the clamp. Widening the opening of the pseudocapsule may ease the extraction of the implant.

Gently but securely grasp the implant with the sterile mosquito clamp and extract the implant.



Dispose of the implant in a proper manner, treating it like any other bio-waste.

Briefly cover the site with a sterile gauze pad and apply pressure to ensure hemostasis.

If inserting a new implant, see the **Suggested Insertion Procedure** instructions provided above. Note that you can insert the new implant into the same "pocket" as the removed implant, or make a new incision at a different site in the same arm or in the contralateral arm.

If a new implant is not to be inserted, proceed to close the incision.

Closing the Incision

To close the incision, you can use the absorbable sutures and/or the sterile adhesive surgical strips provided. To improve adhesion of the strips, you can apply benzoin tincture antiseptic (provided) to the skin, and let it dry, before applying the adhesive strips.



Once closed, cover the incision site with sterile gauze pads and secure the dressing with the bandage provided.

3 DOSAGE FORMS AND STRENGTHS

SUPPRELIN LA is a sterile, nonbiodegradable, diffusion-controlled, hydrogel polymer reservoir drug delivery system designed to deliver histrelin acetate continuously for 12 months after subcutaneous implantation. The sterile implant contains 50 mg histrelin acetate and delivers approximately 65 mcg histrelin acetate per day over 12 months.

4 CONTRAINDICATIONS

SUPPRELIN LA is contraindicated in:

- Patients who are hypersensitive to gonadotropin releasing hormone (GnRH) or GnRH agonist analogs
- Pregnancy [see Use in Specific Populations (8.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Initial Agonistic Action

SUPPRELIN LA, like other GnRH agonists, initially causes a transient increase in serum concentrations of estradiol in females and testosterone in both sexes during the first week of treatment. Patients may experience worsening of symptoms or onset of new symptoms during this period. However, within 4 weeks of histrelin therapy, suppression of gonadal steroids occurs and manifestations of puberty decrease.

5.2 Implant Breakage

Implant insertion is a surgical procedure and it is important that the insertion instructions are followed to avoid potential complications. The insertion and removal of the implant should be done aseptically. Proper surgical technique is critical in minimizing adverse events related to the insertion and the removal of the histrelin implant. On occasion, localizing and/or removal of implant products have been difficult and imaging techniques were used, including ultrasound, CT, or MRI (note: the histrelin implant is not radiopaque). In some cases the implant broke during removal and multiple pieces were recovered. Confirm that the entire implant has been removed. If the implant was not retrieved completely, the remaining pieces should be removed following the instructions in the Suggested Removal Procedure section [see Dosage and Administration (2.2)]. Rare events of spontaneous extrusion of the implant have been observed in clinical trials. During SUPPRELIN LA treatment, patients should be evaluated for evidence of clinical and biochemical suppression of CPP manifestations (see Section 5.6, Monitoring and Laboratory tests). Detailed instructions on the insertion and removal procedures of the implant are provided above [see Dosage and Administration (2.2)].

5.3 Psychiatric Events

Psychiatric events have been reported in patients taking GnRH agonists, including SUPPRELIN LA. Postmarketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment with SUPPRELIN LA [see Adverse Reactions (6)].

5.4 Convulsions

Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists, including SUPPRELIN LA. Reports with GnRH agonists have included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

5.5 Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

Pseudotumor cerebri (idiopathic intracranial hypertension) have been reported in pediatric patients receiving GnRH agonists. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

5.6 Monitoring and Laboratory Tests

LH, FSH and estradiol or testosterone should be monitored at 1 month post implantation then every 6 months thereafter. Additionally, height (for calculation of height velocity) and bone age should be assessed every 6-12 months.

6 ADVERSE REACTIONS

The following serious adverse reactions are described here and elsewhere in the label:

- Initial Agonist Action [see Warnings and Precautions (5.1)]
- Implant Breakage [see Warnings and Precautions (5.2)]
- Psychiatric Events [see Warnings and Precautions (5.3)]
- Convulsions [see Warnings and Precautions (5.4)]
- Pseudotumor Cerebri (Idiopathic Intracranial Hypertension) [see Warnings and Precautions (5.5)]

6.1 Overall Adverse Reaction Profile

The most common adverse reactions with SUPPRELIN LA involved the implant site. Local reactions after implant insertion include bruising, pain, soreness, erythema and swelling.

During the early phase of therapy, gonadotropins and sex steroids rise above baseline because of the natural stimulatory effect of the drug. Therefore, an increase in clinical signs and symptoms may be observed [see Warnings and Precautions (5.1)].

6.2 Adverse Reactions in Clinical Trials

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of SUPPRELIN LA in children with CPP was evaluated in two single-arm clinical trials conducted in a total of 47 patients (44 females and 3 males) over a period of time ranging from 9 to 18 months. The most commonly reported adverse reaction was implant site reaction, which was reported by 24 of 47 (51.1%) patients. Implant site reaction includes discomfort, bruising, soreness, pain, tingling, itching, implant area protrusion and swelling. Two subjects experienced a serious adverse reaction: 1 subject who coincidentally had Stargardt's Disease experienced amblyopia and 1 subject had a benign pituitary tumor (pituitary adenoma). One subject discontinued the study due to an adverse reaction of infection at the implant site. There were no clinically meaningful findings in standard clinical hematology and chemistry tests and/or in vital signs. The incidence of implantation adverse events reported by more than 2 patients are summarized in Table 1.

Table 1: Incidence of implantation adverse reactions reported by ≥ 2 patients treated with SUPPRELIN LA in both clinical trials

Adverse Reactions	N=47
	N (%)
Implant site reaction	24 (51.1)
Keloid scar	3 (6.4)
Scar	3 (6.4)
Suture related complication	3 (6.4)
Application site pain	2 (4.3)
Post procedural pain	2 (4.3)

The following adverse reactions were reported as possibly related or related in 1 patient each: wound infection, breast tenderness, dysmenorrhea, epistaxis, erythema, feeling cold, gynecomastia, headache, menorrhagia, migraine, mood swings, pituitary tumor benign, pruritus, weight increased, disease progression and influenza-like illness. The adverse reaction metrorrhagia was reported as possibly related or related in 2 patients.

6.3 Post-marketing Experience

The following adverse reactions have been identified during post approval use of SUPPRELIN LA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

General Disorders and Administration Site Conditions: implant breakage

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Psychiatric Disorders: Emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression.

Nervous System Disorders: seizures. Pseudotumor cerebri (idiopathic intracranial hypertension) have been observed with GnRH agonists.

7 DRUG INTERACTIONS

Overview: No formal drug-drug, drug-food, or drug-herb interaction studies were performed with SUPPRELIN LA.

<u>Drug-Laboratory Interactions</u>: Therapy with SUPPRELIN LA results in suppression of the pituitary-gonadal system. Results of diagnostic tests of pituitary gonadotropic and gonadal functions conducted during and after SUPPRELIN LA therapy may be affected. SUPPRELIN LA decreased mean serum insulin-like growth factor-1 (IGF-1) levels by approximately 11% in one study (Study 1). SUPPRELIN LA increased the serum concentration of dehydroepiandrosterone (DHEA) in 8 of 36 patients in another study (Study 2).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

SUPPRELIN LA is contraindicated during pregnancy [see Contraindications (4)] since expected hormonal changes that occur with SUPPRELIN LA treatment increase the risk for pregnancy loss. The limited data with histrelin use in pregnant women are insufficient to determine a drug-associated risk for major birth defects or adverse developmental outcomes. Consistent with mechanism of action for SUPPRELIN LA [see Clinical Pharmacology (12.1)], animal reproduction studies showed an increase in fetal loss at clinically relevant exposures.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

Histrelin acetate administered to pregnant rats during the period of organogenesis increased fetal mortality and post-implantation loss at doses of 1, 3, 5 or 15 mcg/kg/day, approximating clinical exposure based on body surface area. These dosages also reduced maternal body weight gain, stimulated ovarian follicular development, increased placental weight and caused abnormal morphology and an increase in fetal size. Histrelin acetate administered to pregnant rabbits during the period of organogenesis increased fetal mortality and abortion/early termination at the two highest doses and caused total litter loss at all doses of 20, 50 or 80 mcg/kg/day (approximately 3- to 12-times clinical exposures based on body surface area).

8.2 Lactation

Risk Summary

There are no data on the presence of SUPPRELIN LA in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Absorption and systemic activity are not expected from potential exposure to the peptide, histrelin, in the breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SUPPRELIN LA and any potential adverse effects on the breastfed child from SUPPRELIN LA or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients below the age of 2 years have not been established. The use of SUPPRELIN LA in children under 2 years is not recommended.

10 OVERDOSAGE

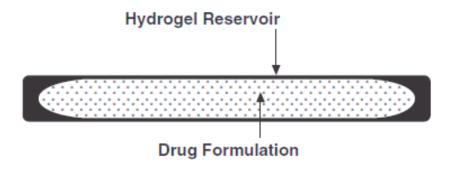
There have been no reports of overdose in SUPPRELIN LA clinical trials. High doses of histrelin acetate injection in animal studies were generally associated only with effects attributed to the expected pharmacology. The method of drug delivery makes accidental or intentional overdosage unlikely.

11 DESCRIPTION

SUPPRELIN LA is a sterile, non-biodegradable, diffusion-controlled, hydrogel polymer reservoir containing histrelin acetate, a synthetic nonapeptide analog of the naturally occurring gonadotropin releasing hormone (GnRH) possessing a greater potency than the natural sequence hormone. SUPPRELIN LA is designed to deliver approximately 65 mcg histrelin acetate per day over 12 months.

The SUPPRELIN LA implant looks like a small thin flexible tube and consists of a 50-mg histrelin acetate drug core inside a 3.5 cm by 3 mm, cylindrical, hydrogel polymer reservoir (Figure 1). The implant may appear partially to completely full with variation in color from off-white to light brown. The color may be uneven within the core.

Figure 1. SUPPRELIN LA Implant Diagram (not to scale)



The chemical name of histrelin acetate is: L-Pyroglutamyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-N-benzyl-D-histidyl-L-leucyl-L-arginyl-L-proline N-ethylamide, acetate salt.

The molecular formula for histrelin acetate is $C_{66}H_{86}N_{18}O_{12} \times 2$ CH₃COOH and its molecular weight is 1443.70 (or 1323.52 as free base). Histrelin is also chemically described as 5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-Nt-benzyl-D-histidyl-L-leucyl-L-arginyl-N-ethyl-L-prolinamide diacetate. The chemical structure of the free base (histrelin) is represented below in Figure 2.

Figure 2. Structure of Histrelin

The drug core also contains the inactive ingredient stearic acid NF. The hydrogel polymer reservoir is a hydrophilic cartridge composed of 2-hydroxyethyl methacrylate, 2-hydroxypropyl methacrylate, trimethylolpropane trimethacrylate, benzoin methyl ether, Perkadox-16, and Triton X-100. Each implant is packaged hydrated in a glass vial containing 2 mL of sterile 1.8% sodium chloride solution, so that it is primed for immediate release of the drug upon insertion.

A single use, sterile, Insertion Tool is provided along with the implant that can be used for the placement of the SUPPRELIN LA implant into the subcutaneous tissue of the inner aspect of the upper arm. The Insertion Tool is enclosed in a sterile bag and is provided separately from the implant in the Implantation Kit [see Recommended Procedure for Implant Insertion and Removal (2.2)].

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

SUPPRELIN LA is a GnRH agonist and an inhibitor of gonadotropin secretion when given continuously. It delivers approximately 65 mcg histrelin acetate per day. Both animal and human studies indicate that following an initial stimulatory phase, chronic, subcutaneous administration of histrelin acetate desensitizes responsiveness of the pituitary gonadotropin which, in turn causes a reduction in ovarian and testicular steroidogenesis.

In humans, administration of histrelin acetate results in an initial increase in circulating levels of LH and FSH, leading to a transient increase in concentration of gonadal steroids (testosterone and dihydrotestosterone in males, and estrone and estradiol in premenopausal females).

However, continuous administration of histrelin acetate causes a reversible down-regulation of the GnRH receptors in the pituitary gland and desensitization of the pituitary gonadotropes. These inhibitory effects result in decreased levels of LH and FSH.

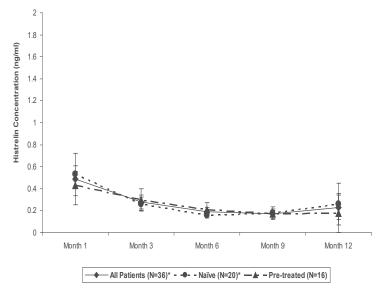
12.2 Pharmacodynamics

Long-term treatment with histrelin acetate suppresses the LH response to GnRH causing LH levels to decrease to prepubertal levels within 1 month of treatment. As a result, serum concentrations of sex steroids (estrogen or testosterone) also decrease. Consequently, secondary sexual development ceases to progress in most patients. Additionally, linear growth velocity is slowed which improves the chance of attaining predicted adult height.

12.3 Pharmacokinetics

Pharmacokinetics of histrelin after implantation of SUPPRELIN LA was evaluated in a total of 47 children with CPP (11 subjects in Study 1 and 36 subjects in Study 2). Patients were examined at 4 weeks after implant insertion and a few times throughout the treatment period. Median serum histrelin concentrations remained above the limit of quantification for the treatment period. Histrelin acetate levels were sustained throughout the study period for most subjects (Figure 3). The median of maximum serum histrelin concentrations over the study period was 0.43 ng/mL, which is expected to maintain gonadotropins at prepubertal levels. There was no apparent pharmacokinetic difference between naïve subjects to a LHRH agonist treatment and subjects who had previous treatment with a LHRH agonist (Figure 3).

Figure 3. Mean and Standard Deviation of Serum Histrelin Concentrations (ng/mL) Results at Each Visit



13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies were conducted in rats for 2 years at doses of 5, 25 or 150 mcg/kg/day (up to 11 times human exposures using body surface area comparisons, based on a 65 mcg/day dose in humans) and in mice for 18 months at doses of 20, 200, or 2000 mcg/kg/day (at less than therapeutic exposure to 70 times human exposure using body surface area comparisons, based on a 65 mcg/day dose in humans). As seen with other GnRH agonists, histrelin injection administration was associated with an increase in tumors of hormonally responsive tissues. There was a significant increase in pituitary adenomas in rats at mid and high doses (2-11 times human exposure based on body surface area comparisons with a 65 mcg/day human dose). There was an increase in pancreatic islet-cell adenomas in treated female rats and a non-dose-related increase in testicular Leydig-cell tumors (highest incidence in the low-dose group). In mice, there was significant increase in mammary-gland adenocarcinomas in all treated females. In addition, there were increases in stomach papillomas in male rats given high doses, and an increase in histiocytic sarcomas in female mice at the highest dose.

Mutagenicity studies have not been performed with histrelin acetate. Saline extracts of implants with and without histrelin acetate were negative in a battery of genotoxicity studies. Fertility studies have been conducted in rats and monkeys given subcutaneous daily doses of histrelin acetate up to 180 mcg/kg/day (up to 13 and 30 times human exposure, respectively using body surface area comparisons, based on a 65 mcg/day human dose) for 6 months and full reversibility of fertility suppression was demonstrated. The development and reproductive performance of offspring from parents treated with histrelin acetate has not been investigated.

14 CLINICAL STUDIES

The efficacy of SUPPRELIN LA in children with CPP has been evaluated in two single-arm, open label studies. Study 1 was conducted in 11 pretreated female patients, 3.7 to 11.0 years of age. Study 2 was conducted in 36 patients (33 females and 3 males), 4.5 to 11.6 years of age. Sixteen pretreated and 20 treatment-naïve patients were enrolled in Study 2. Baseline patient characteristics were typical of patients with CPP. Efficacy assessments were similar in both studies and included endpoints that measured the suppression of gonadotropins (luteinizing hormone and follicle stimulating hormone) and gonadal sex steroids (estrogen in girls and testosterone in boys, respectively) on treatment. Other assessments were clinical (evidence of stabilization or regression of signs of puberty) or gonadal steroid-dependent (bone age, linear growth). In Study 2, the primary measure of efficacy was LH suppression.

In Study 2, suppression of LH was induced in all treatment naïve subjects and maintained in all pretreated subjects at Month 1 after implantation and continued through Month 12 (suppression was defined as a peak LH < 4 mIU/mL following stimulation with the GnRH analog leuprolide acetate).

Secondary efficacy hormone assessments (FSH, estradiol and testosterone) and additional efficacy assessments (bone age advancement, linear growth, clinical progression of puberty) indicated stabilization of disease. Estradiol suppression was present in all 33 girls (100%) through Month 9 and 97% at Month 12. Testosterone suppression was maintained in the three pre-treated males participating in Study 2. The SUPPRELIN LA effect on efficacy endpoints in the Study 1 was consistent with that observed in Study 2.

16 HOW SUPPLIED/STORAGE AND HANDLING

SUPPRELIN LA (NDC 67979-002-01) is supplied in a corrugated shipping carton that contains 2 inner cartons: a small one for the vial containing the SUPPRELIN LA implant, which is shipped with a cold pack inside a polystyrene cooler that must be refrigerated upon arrival, and a larger one comprising the Implantation Kit, which must *not* be refrigerated, for use during insertion or removal of SUPPRELIN LA.

The SUPPRELIN LA implant contains 50 mg of histrelin acetate. The SUPPRELIN LA implant carton contains a cold pack for refrigerated shipment and a small carton containing an amber plastic pouch. Inside the pouch is a glass vial with a Teflon-coated stopper and an aluminum seal, containing the implant in 2 mL of sterile 1.8% sodium chloride solution. (**Note**: The 3.5 mL vial is not completely filled with saline).

Upon receipt, refrigerate the small carton containing the amber plastic pouch and glass vial (with the implant inside) until the day of insertion. The implant vial should not be opened until just before the time of insertion.

SUPPRELIN LA is stable when stored refrigerated, in its sealed vial, pouch, and carton, at 2-8°C (36-46°F) until the expiration date provided. Excursion permitted to 25°C (77°F) for 7 days. Do not freeze. Protect from light.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-Approved patient labeling (Medication Guide).

Initial Agonistic Action

Patients should be advised that a transient worsening of symptoms of puberty or onset of new symptoms may occur initially. However, within 4 weeks of histrelin therapy, complete suppression of gonadal steroids occurs and manifestations of puberty decrease [see Warnings and Precautions (5.1)].

Post-insertion Care

Patients should be instructed to refrain from getting the inserted arm wet for 24 hours and from strenuous exertion of the inserted arm for 7 days after implant insertion to allow the incision to fully close. The adhesive elastic bandage can be removed at that time. The patient should not remove the surgical strips; rather, the strips should be allowed to fall off on their own after several days.

Psychiatric Adverse Events

Inform caregivers that symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression, have been observed in patients receiving GnRH agonists, including SUPPRELIN LA. Alert caregivers to the possibility of development or worsening of psychiatric symptoms, including depression, during treatment with SUPPRELIN LA [see Warnings and Precautions (5.3), Adverse Reactions (6.3)].

Convulsions

Inform caregivers that reports of convulsions have been observed in patients receiving GnRH agonists, including SUPPRELIN LA. Patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions may be at risk [see Warnings and Precautions (5.4)].

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

Inform patients and caregivers that reports of pseudotumor cerebri (idiopathic intracranial hypertension) have been observed in pediatric patients receiving GnRH agonists. Advise patients and caregivers to monitor for headache, and vision issues such as blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement, ringing in the ears, dizziness, and nausea. Advise patients and caregivers to contact their healthcare provider if the patient develops any of these symptoms. [see Warnings and Precautions (5.5)].

Common Adverse Reactions

Patients should be advised to report to their physician any severe pain, redness, or swelling in and around the implant site. Infrequently, SUPPRELIN LA may be expelled from the body through the original incision site, rarely without the patient noticing. The patient should be instructed to monitor the incision site until it is healed. The patient should also return for routine checks of their condition and to ensure that SUPPRELIN LA is present and functioning in his/her body [see Adverse Reactions (6.1)].

For more information, call 1-800-462-3636 or visit www.supprelinla.com.

Distributed by: Endo Pharmaceuticals Inc. Malvern, PA 19355 USA

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Revised: 04/2022

EXHIBIT K

Reproductive Technologies, Inc. 2115 Milvia Street, Suite 201 Berkeley CA 94704-1157

Tel. (510) 841-1858 - Fax (510) 841-0332 e-mail: info@thespermbankofca.org Website: www.thespermbankofca.org

Invoice

Invoice	INV00965	
Date	3/1/2021	
Page	1	
Req. Ship Date	3/1/2021	
	0/0/0000	

Bill To:

HISTORICAL

Hudacko, Spencer (Gemma) Spencer (Gemma) Hudacko 1708 Lexington Ave Apt #4

El Cerrito, CA 94530 United States **Ship To:** (000) 000-0000 Ext. 0000 Hudacko, Spencer (Gemma)

1708 Lexington Ave Apt #4

El Cerrito, CA

94530

Purchase C	Order No.	Customer I	D	Salesperson I	0	Shipping Method	Payment Te	rms	Rea	Ship Date	Master No.
AB		94971	-			ANNUAL STORAGE	Net 15		3/1/2	021	52,024
Ordered	Shipped	B/O	Item Num	ber	Desc	ription	1	Disco	unt	Unit Price	Ext. Price
1	1	0	DD ORIEN	ITATION/INITIA	DD c	onsultation and account			\$0.00	\$900.00	
1	1	0	4		Blood	d Panels 1 and 4 and Uri	ne CT/GC		\$0.00	\$650.00	
1	1	0	CLIENT S	TORAGE (1 YE	Annı	ial Storage 2020-2021			\$0.00	\$450.00	
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You have set up a Sperm Storage Account. Today's fees cover the first 12 months of Storage. 2/23/21 Four vials aded to your account. Thanks!

Subtotal		\$2,000.00
Misc	Dan	\$0.00
Tax		\$0.00
Freight		\$0.00
Trade Discount		\$0.00
Total		\$2,000,00



2115 Milvia Street, Suite 201 Berkeley CA 94704-1157

Phone 510.841.1858
Fax 510.841.0332
billing@tsbca.org
www.thespermbankofca.org

Invoice

Invoice	SINV22-1483
Date	February 18, 2022
Page	1
Req. Ship Date	
Req. Arrival Date	

Bill To: Ship To:

Hudacko, Spencer (Gemma) 1708 Lexington Ave Apt #4 El Cerrito CA, 94530 Hudacko, Spencer (Gemma) 1708 Lexington Ave Apt #4 El Cerrito CA, 94530 Phone No. 41599912260000

Cust ID	Health Worker	Shipping Method	Payment Terms
94971	SO		Credit Card (eBiz
			Charge)

		Total \$	500.00
Annual Storage 2022-2023	1 Each	500.00	500.00
Description	Quantity Unit	Unit Price	Amount

Invoice is Paid

EXHIBIT L

RICHARDSON/SPRGFLD SRVC CNTR PO BOX 30555 SALT LAKE CITY, UT 84130-0555 www.myuhc.com

Address Change? Please contact your employer's benefit department. 259HSEPRT1001003-10470-01 EDWARD HUDACKO

ATTN QMCSO PO BOX 30333 TAMPA FL 33630-3333



Member ID 945022269

Statement Period 06/17/21 - 09/15/21



Customer Care 1-866-348-1286

Productive Dr. Visits

Be sure to make the most of your doctor visits, Before you go, write down when your problem began, your symptoms, what might have led to the problem and any prescription or over-the-counter drugs or vitamins/supplements you take. During your visit, bring up your main issue first and then tell your doctor about any recurring problems. Listen carefully and ask questions. This is a great way to build a relationship with your doctor and be proactive in your health care.

Medical claims where payments may be needed from you:

Claims processed between 06/17/21 to 09/15/21	Pay your provider(s) when they bill you	Applied To Deductible
06/25/21 services for CHRISTINE provided by 'A GOLD' Claim Number: 0CT3213670101 Provider Billed: \$325.00 Payments and Discounts: -\$128.45	\$196.55	\$122.54
08/18/21 services for CHRISTINE provided by 'J IOCCO' Claim Number: 0CW7568809201 Provider Billed: \$230.00 Payments and Discounts: -\$110.00	\$120.00	\$0.00
08/18/21 services for CHRISTINE provided by 'J IOCCO' Claim Number: 0CW7568809201 Provider Billed: \$230.00 Payments and Discounts: -\$147.50	\$82.50	\$0.00
08/24/21 services for CHRISTINE provided by 'J IOCCO' Claim Number: 0CW9632834401 Provider Billed: \$230.00 Payments and Discounts: -\$110.00	\$120.00	\$0.00
08/24/21 services for CHRISTINE provided by 'J IOCCO' Claim Number: 0CW9632834401 Provider Billed: \$230.00 Payments and Discounts: -\$147.50	\$82.50	\$0.00
06/24/21 services for SPENCER provided by 'GOLDEN STATE' Claim Number: 0CT1641820101 Provider Billed: \$265.10 Payments and Discounts: -\$122.95	\$142.15	\$142.15

Please see the next page for more information Page 1 of 8

UHG-0700406-00175638-P

0000016214092-259HSEPRT10010031047001

Medical claims where payments may be needed from you: continued

Claims processed between 06/17/21 to 09/15/21	Pay your provider(s) when they bill you	Applied To Deductible
08/04/21 services for SPENCER provided by 'I LEE' Claim Number: 0CW3504121601 Provider Billed: \$745.00 Payments and Discounts: -\$672.62	\$72.38	\$0.00
08/04/21 services for SPENCER provided by 'I LEE' Claim Number: 0CW3504121602 Provider Billed: \$209,820.34 Payments and Discounts: -\$207,857.08	\$1,963.26	\$0.00
08/11/21 services for SPENCER provided by 'E AICARDI' Claim Number: 0CW5115036302 Provider Billed: \$20.00 Payments and Discounts: -\$18.00	\$2,00	\$0.00
08/18/21 services for SPENCER provided by 'J IOCCO' Claim Number: 0CW7568759501 Provider Billed: \$230.00 Payments and Discounts: -\$110.00	\$120.00	\$0.00
08/18/21 services for SPENCER provided by 'I IOCCO' Claim Number: 0CW7568759501 Provider Billed: \$230.00 Payments and Discounts: -\$147.50	\$82.50	\$0.00
08/24/21 services for SPENCER provided by 'J IOCCO' Claim Number: 0CW9632800301 Provider Billed: \$230.00 Payments and Discounts: -\$110.00	\$120.00	\$0.00
08/11/21 services for WILLIAM provided by 'E AICARDI' Claim Number: 0CW5115036402 Provider Billed: \$20.00 Payments and Discounts: -\$18.00	\$2.00	\$0.00
Total:	\$3,105.84	\$264.69

For more information about these claims, please refer to the Explanation of Benefits or visit: www.myuhc.com.

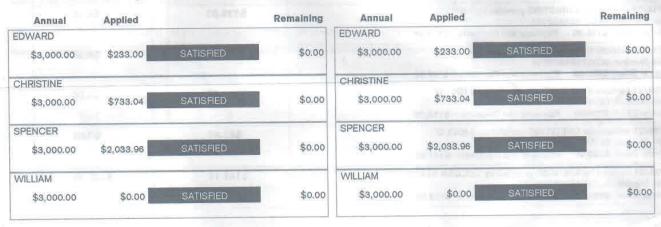
This is not a bill. Your provider will bill you directly unless you have already paid them. Please check your records. These charges represent your responsibility as defined by your health benefit plan. They may include your deductible, coinsurance, or a product or service that is not an eligible expense. If you have coverage with another insurance carrier or Medicare, these charges may not include any product or service in which the other insurance carrier or Medicare was primary. In addition, the amount in the "Pay your provider(s) when they bill you" area above may include payments made to the subscriber. Please see your coverage documents for more information.

Tracking Your Deductibles and Maximums

Your Deductibles as of 09/15/21 for Plan Year 01/01/21 - 12/31/21

In-Network (Medical/Rx Combined)

Out-of-Network



Please see the next page for more information Page 2 of 8 Customer Care 1-866-348-1286

UHG-0700406-00175638-P

0000016214092-259HSEPRT10010031047002

EXHIBIT M

7/16/22, 1:03 PM

Re: [Q] Fertility Preservation ?? was Re: update on Spence... - Ted Hudacko

Re: [Q] Fertility Preservation ?? was Re: update on Spencer's health.

Ted Hudacko

Thu 11/11/2021 5:46 PM

To: Daniel S. Harkins <dshark1@pacbell.net>;

Bcc:Paula <Paula@samedaylegal.net>; Susan <Susan@samedaylegal.net>;

Dear Mr. Harkins,

I phoned you today and we spoke very briefly. The reason for my call was that you had not replied to my voice message left for you in October requesting a call back. I also have sent you two emails in November. I am not represented so you are not forbidden to speak to me as you claimed when I attempted to speak to you in July 2019. I don't know what you mean by your comment today that I was using a "tone" with you. This is absurd and simply evasiveness by you.

Spencer, my son and whom you represent, is being sterilized by the administration of Supprellin LA implant. You indicated today you had not read either my November emails, nor were aware of the procedure Spencer had, nor had consulted with either Spencer nor Christine Hudacko, the mother either before or since Spencer's procedure. The custody orders do not permit sterilization. The orders also do not permit surgery which the implant procedure is a minor surgery requiring anaesthesia.

Supprellin is the trade name for histrelin acetate and is as I attempted to explain to you today, not approved by the FDA for uses other than Central Precocious Puberty (CPP) in boys 11 and younger or Prostate Cancer in older men. Neither apply to Spencer who is 17 and undergoing normal, not precocious puberty. The other notorious use for histrelin acetate is chemical castration of convicted sex offenders. I attempted to explain this to you and asked why are you allowing my son to be sterilized? You didn't answer my question but instead made your comment about "tone," stated you did not have to speak with me, then hung up.

I'd like some answers from you how and why you are allowing Spencer to be sterilized? Spencer is a deeply troubled teenager and cannot possibly understand the consequences what this means. The permanent and irreversible effect of histrelin acetate is accomplished in as little as four months, meaning that Spencer already has had this implant 3 months. Not only will this render Spencer incapable of reproduction, but incapable of sexual response and orgasm. I cannot believe that you are not aware of Spencer's status of health and were apparently unaware that this procedure had taken place nor could represent that you verified Spencer understood the consequences and can properly give informed consent.

You have accepted a substantial amount of payment from me in the form of many checks. I don't have the exact sum handy but I reckon it is in the tens of thousands of dollars so far. What are you doing? You have a duty to protect Spencer. I would like answers.

Ted Hudacko c: 408.482.0412

From: Ted Hudacko

Sent: Monday, November 1, 2021 9:29 AM To: Daniel S. Harkins; Nathaniel Bigger

 $https://na02.msexchangeoutlook.com/owa/\#viewmodel=ReadMessageItem\&ItemID=AAMkADBmZjgzOWE0LTk4MjAtNDgyMy1hY2FlLTZkMDZiZmYyMDk2Y... \ \ 1/2 and 1/2 an$

Case 3:23-cv-05316-SI Document 90 Filed 08/30/24 Page 109 of 139

7/16/22, 1:03 PM Re: [Q] Fertility Preservation ?? was Re: update on Spence... - Ted Hudacko

Cc: Christine Hudacko

Subject: [Q] Fertility Preservation ?? was Re: update on Spencer's health.

Dear. Mr. Bigger and Mr. Harkins,

Please provide a more detailed update re: Spencer and the procedures that have been performed and ongoing and the counseling prior to starting GNRHa (aka "puberty blockade", aka "anti androgen"). As you know I have voiced concern re: lack of safety for this category of drugs. This is the exact same protocol as is administered to convicted sex offenders to accomplish chemical sterilization. I have specifically asked Christine twice via text message what "fertility preservation efforts were made for Spencer as what Christine has done without my consent and knowledge will destroy Spencer's reproductive viability. Christine has ignored my inquiries. Why are you sterilizing Spencer?

Endocrine society recommendations subscribed to by WPATH, Hembree et al 2017: "We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 $|\oplus \oplus \ominus \bigcirc$)" It is in fact one of the only 3 recommendations that is not low or very low quality or ungraded out of the 27. So am I to understand that UCSF is not even following WPATH guidelines? Mr. Harkins you have a duty to protect Spencer and it was your Minor's Counsel report that extolled the high quality of WPATH SOC. I would appreciate answers.

Ted

From: Christine Hudacko <christinehudacko@yahoo.com>

Sent: Monday, October 18, 2021 7:47 PM

To: Ted Hudacko

Cc: Nathaniel Bigger; Daniel S. Harkins Subject: update on Spencer's health

Ted, Spencer has begun hormone therapy - testosterone blocker (Supprelin) via an implant and estrogen via pills (Estradiol). Spencer is doing well and happy to finally begin the process. I believe that Spencer has been very supported by UCSF and therapists over the past 12 months in determining this was the right step for them. Spencer continues to see Dr. Barrow to be supported. Insurance has paid for the vast majority of implant procedure and I sent UCSF a check for the balance (\$2035.64). I don't expect that you will pay for half given your disapproval of transitioning.

Spencer started HRT in Aug. and I waited to tell you to be able to report how it is going so far. I also waited because frankly I am concerned how you will react and potentially act out to our children and me. Friday night's incident of you harassing me, with Will witnessing some of it, confirms my concerns and that Will will have to resume therapy with Adam when football concludes. -Chris

Sent from Mail for Windows

EXHIBIT N

UCSF MyChart - Visit Summary 1/30/22, 8:23 PM

Name: Gemma Hudacko | DOB: 6/10/2004 | MRN: 45479935 | PCP: Eileen G. Aicardi, MD

A Note to Patients: Symptoms are concisely summarized to inform treatment recommendations. For reasons of privacy and brevity, this note does not attempt to capture all experiences that were discussed.

Progress Notes

Stephen M Rosenthal at 11/9/2021 4:00 PM

Subjective:

Subjective

Chief Complaint
Patient presents with

Follow-up

I performed this evaluation using real-time telehealth tools, including a live video Zoom connection between my location and the patient's location. Prior to initiating, the patient consented to perform this evaluation using telehealth tools.

HPI 17 y.o. 4 m.o. transgender female. Last seen 6/8/21. Started blocker + E2 8/21.

Currently in 12th grade; looking at colleges now. Interested in becoming a nurse.

Recent Hx followed by Dr. Karissa Barrow. No active plan or intent. No longer feeling suicidal since starting lexapro. Also followed by Dr. Dan Karasic (psychiatrist). Doing DBT (group) as well.

Patient's allergies, medications, past medical, surgical, family and social histories were reviewed and updated as appropriate.

Review of Systems

Objective:

Objective

There were no vitals taken for this visit.

Physical Exam

Lab Review:

Labs ordered 10/20/21 at Mother's request via LabCorp (in Berkeley): T, E2, Prolactin-11/5/21--Results not yet in chart.

https://ucsfmychart.ucsfmedicalcenter.org/UCSFMyChart/inside.asp...4sKEO6aLyo1VI3rR81Mrr13rF3EdqseV5XpkRmtYdg7I%2D3D&printmode=true

Page 1 of 2

UCSF MyChart - Visit Summary 1/30/22, 8:23 PM

Assessment:

Assessment

17 y.o. 4 m.o. transgender female; doing well.

Plan:

Plan

Have asked Alice Lau to track down results of recent labs.

Continue current Rx pending above.

RTC 3 months.

I spent a total of 30 minutes on this patient's care on the day of their visit excluding time spent related to any billed procedures. This time includes time spent with the patient as well as time spent documenting in the medical record, reviewing patient's records and tests, obtaining history, placing orders, communicating with other healthcare professionals, counseling the patient, family, or caregiver, and/or care coordination for the diagnoses above.

MyChart® licensed from Epic Systems Corporation © 1999 - 2022

EXHIBIT O

Edward Hudacko 3030 Clinton Avenue Richmond, California [94804] C: +1 408.482.0412 E: ted.hudacko@ieee.org

October 21, 2020

Dr. Stephen M. Rosenthal, M.D., Medical Director of the CAGC Diane Ehrensaft, PhD., Mental Health Director of the CAGC UCSF Benioff Children's Hospital Child and Adolescent Transgender Center Clinic Ron Conway Family Gateway Medical Building 1825 Fourth St., Sixth Floor San Francisco, California [94158]

Re: Spencer Hudacko treatment/research questions. MyChart proxy form.

Dear Drs. Rosenthal and Ehrensaft,

Thank you for meeting with my minor child, Spencer Hudacko, and Spencer's mother, Christine Hudacko, on 10/13/2020. I regret I was unable to participate. I hope this can be a cordial and constructive exchange. I have questions and concerns that I hope you will address promptly.

Please find enclosed my completed proxy form for MyChart record access re: Spencer. I was informed that I need to provide this to Spencer's doctor(s) in order to gain access. I appreciate your assistance in this regard.

Has Spencer been given a coded diagnosis by either you or another professional? If so, what is the diagnosis, or diagnoses? If by another professional, who? What is your relationship with this third party? What assessments were made in reaching a diagnosis? What assessments have been recommended as next steps? I have not seen any of the reports for Spencer, thus my interest and so I can be assured Spencer has a full differential diagnosis that can be validated.

I reviewed the paper you co-authored describing the four-site collaborative research network for longitudinal observational study of transgender and gender-diverse (TGD) youth undergoing medical interventions to address gender dysphoria. Tables 2 and 4 of your paper enumerate Physiologic and Anthropometric Data and Mental and Behavioral

¹ "Creating the Trans Youth Network: A Collaborative Research Effort" *Transgend. Health* 2019 Nov 1;4(1):304-312. doi: 10.1089/trgh.2019.0024. eCollection 2019. Attached here as Exhibit A. Online at: https://pubmed.ncbi.nlm.nih.gov/31701011/ and https://www.liebertpub.com/doi/pdf/10.1089/ trgh.2019.0024

Health Measures for the later pubertal cohort that Spencer presumably falls within. I welcome the opportunity to review these artifacts in Spencer's case for my better understanding.

Is Spencer being assessed and treated in the context of standard, generally-accepted, non-controversial and approved medical care and practice? Or, is Spencer enrolled (either formally or informally) as a test subject for your stated goal of "collecting data?" Has Spencer's mother, Christine, given consent for Spencer's participation as a test subject in the NIH-funded study in which Dr. Rosenthal is named as a Principal Investigator (PI) or any other study? Please identify fully the study or studies.

Consent to standard and recognized medical treatment protocols and consent to participation in a research experiment involving pre-approval therapeutic and pharmaceutical protocols are two very different things. The latter should involve a more thoughtful decision process and include the consent of *both* parents of a minor whom is being considered for any experimental treatment. It is unclear if this distinction and the experimental nature of the study underway at UCSF and other the three sites sharing in NIH grant project 5R01HD082554-05 were known to the Contra Costa Family Court when Judge Hiramoto granted temporary sole legal custody to Christine of Spencer on either 6/24/2020 or 8/26/2020.

The latter is an interesting question that unfortunately came up neither in pleadings nor during hearings. Significantly, Judge Hiramoto extended Christine's legal custody to include decisions over hormonal transition treatment at the 8/26/2020 hearing while continuing to limit decisions over surgical treatment. I'm bringing the question up now as everyone else in this matter appears to have been a few steps ahead to Spencer's and my disadvantage. This is a significant change, and in fact, is a reversal on this aspect from Judge Hiramoto's prior order post the 6/24/2020 hearing that disallowed Christine from having sole legal discretion regarding hormonal treatment.

As you should know, I contacted CAGC and communicated directly with Jessie Cohen of your staff on 7/7/2020, initially by email. Cohen explained I could request a call back from either of you by requesting same at 415-353-7337. I did so the same day, requesting to speak with Dr. Ehrensaft. Dr. Ehrensaft eventually called me more than two months later on or about 9/16/2020 at approximately 10:30 am. We spoke approximately 30 minutes. At the time, I thought ours had been a constructive conversation.

I recently reviewed itemized invoices from Daniel S. Harkins, the court-appointed Minor's Counsel in the divorce and custody matter. Dr. Ehrensaft had phone calls with

² "The Impact of Early Treatment in Transgender Youth," NIH Project 5R01HD082554-05. Project description attached here as Exhibit B. Online at: https://projectreporter.nih.gov/project info description.cfm?aid=9730239&icde=52269515

Mr. Harkins on at least two dates 7/28/2020 and 8/13/2020 for a combined duration longer than Dr. Ehrensaft later spent with me 9/16/2020. I'm at a loss to understand both why Dr. Ehrensaft waited so long to contact me, Spencer's parent, and why you prioritized two conversations with Mr. Harkins much earlier within that period and in advance of the 8/26/2020 follow-up hearing where legal custody was changed adversely.

The 8/26/2020 temporary order gave Christine sole discretion to give authorization and consent for hormonal treatment and at the same time has forbidden my participation in medical appointments involving Spencer. However, "medical appointments" with you may be a misnomer because these also or primarily are participation in experimental research. Your timely communication with Mr. Harkins and less-than-timely communication with me, Spencer's parent, better reflect advancing your own research objectives by enrolling another subject but arguably do not reflect the "best interest of the child," Spencer.

There are better methods of communication, education and persuasion to give assurance and to gain the buy-in of a parent with many questions such as myself. Secrecy, obfuscation and delay are not good means to engender trust. Instead, such methods of subterfuge create additional questions about motivation and intent.

According to your own "Creating the Trans Youth Network" article, "there is a lack of consensus among professionals around timing of initiation of medical interventions, as well as optimal dosing regimens."³

My boldness in posing these questions presents certain personal risk to myself and potentially further jeopardizes my already-degraded parental rights by virtue of an argument you raise earlier in "Creating the Trans Youth Network." You say "[d]istal stressors may include harassment, bullying, ... loss of ... family members ...[and] influence individual/proximal stressors ... which in turn contribute to psychological distress." My questions are rooted in concern for Spencer's health, safety and well-being and the best interest of my child.

Many parents in my situation have similar concerns and questions but are silenced by a chilling effect created as a consequence in which our appropriate parental concerns are mischaracterized or intentionally misrepresented as being at best "unsupportive" but more frequently and defaming as "transphobic" or "bigoted." This appears what has happened in my own case and contributed largely, if not exclusively, to the current, temporary denial of my parental and custodial rights of Spencer.

³ "Creating the Trans Youth Network: A Collaborative Research Effort" *Transgend. Health* 2019 Nov 1;4(1): pg. 305.

Returning to Table 4, it was unclear to me that measurements of cognitive, memory and executive functions are included. These categories are not mentioned under either Construct or Measure. Please clarify.

I notice your citations did not reference the study published in 2017 that observed correlation and likely causal relation between gonadotropin releasing hormone analogs (GnRHa) and decreased cognitive and executive functions.⁴ Table 4 also does not include multiple of the metrics cited by Schneider *et. al.*, e.g., Weschler Scale (WISC-III or WISC-IV), executive function (EF), Tower of London. Without measurement of these attributes, how is it possible to track outcomes in these dimensions? I would like to better understand why your study appears to omit observation of these attributes.

The GnRHa suspected as culprit by Schneider *et. al.* is the same substance, is it not, that you state "lacks consensus among professionals ... of ... *optimal* dosing regimens?" (Emphasis added). There appears to be a lack of consensus among professionals of the *safety* of GnRHa, not just "optimal dosing." Otherwise it appears cognitive function is not a concern of yours. I am very much concerned by this. Are you performing inappropriate human experimentation? Has Spencer or Spencer's mother, Christine, been fully apprised of potential or known risks, including harm to cognitive, memory and executive function? Can Spencer, a minor, give appropriate consent?

Schneider *et. al's*. Background and Discussion sections cite and performed meta-analysis of numerous other human and animal studies including human subject brain diffusion tensor imaging (DTI) to measure white matter fractional anisotropy (FA). The meta-analysis collectively and consistently reinforced or failed to deny their hypothesis of negative impact to brain white matter under pubertal suppression. Schneider *et. al.* conclude, "Further longitudinal clinical studies comparing DTI parameters and cognition among TG adolescents under puberty suppression and age-matched controls with physiological pubertal development are needed in order to confirm the present findings and support the hypothesis on the impact of sex hormones on cognition and brain maturity during developmental stages."

Did you discuss the Schneider *et. al.* article with Mr. Harkins? If so, please provide the details when and the substance of such conversation(s). I shared the article with the family court in my responsive declaration to Minor's Counsel Report. At the 8/26/2020 hearing, Mr. Harkins derisively dismissed Schneider *et. al.* as "the Brazil report", completely failing to address the substance of their cognition warnings.

⁴ "Brain Maturation, Cognition and Voice Pattern in a Gender Dysphoria Case under Pubertal Suppression," Maiko A. Schneider *et. al.* Front Hum Neurosci. 2017; 11: 528. Attached here as Exhibit C and online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5694455/

Is there animal experimental data to pre-validate the safety of GnRHa, especially with respect to cognitive, memory and executive function at any dosage level that provides assurance for human experimentation within known parameters for safety? What are the differences with regard to safety of GnRHa in minors vs. adults?

I support conducting good science for the advancement of humankind and knowledge. However I have doubts about this experimental design, what parameters have been included as well as excluded for observation, as well as concerns about Spencer's participation and our informed consent.

I have come to learn that I am not alone in these concerns.⁵⁶

I hope we can work constructively through the questions and concerns I have raised above regarding Spencer's best interests and that we can engage in an inclusive and respectful manner to avoid and correct any misunderstandings. The bottom line is that I do not want Spencer to be cognitively harmed as a consequence of experimental protocols you may be conducting or intend to conduct on Spencer, the details of which have been withheld from me and to which I have neither been asked nor given informed consent. Mine are proper parental concerns for the safety of my minor child and are only the best interest of Spencer. I look forward to your responses.

Sincerely,

Edward A. Hudacko, Spencer's father.

Threes A Herdrich

Cc: Christine M. Hudacko,

Nathaniel Bigger, Esq.,

Daniel S. Harkins, Esq.,

The Honorable Joni Hiramoto, Superior Court of Contra Costa, California.

The Honorable Mark DeSaulnier, California C.D. 11,

The Honorable Nancy Pelosi, Speaker of the House, California C.D. 12,

The Honorable Barbara Lee, California C.D. 13,

The Honorable Doug LaMalfa, California C.D. 1

⁵ US Congress HR8012 *Protecting Children from Experimentation Act of 2020.* https://trackbill.com/bill/us-congress-house-bill-8012-protecting-children-from-experimentation-act-of-2020/1942605/

⁶ US Congress HR8013 End Taxpayer Funding of Gender Experimentation Act of 2020 https://trackbill.com/bill/us-congress-house-bill-8013-end-taxpayer-funding-of-gender-experimentation-act-of-2020/1942604/

EXHIBIT Q

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UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA NORTHERN DIVISION

REV. PAUL A. EKNES-TUCKER; BRIANNA BOE, individually and on behalf of her minor son, MICHAEL BOE; JAMES ZOE, individually and on behalf of his minor son, ZACHARY ZOE; MEGAN POE, individually and on behalf of her minor daughter, ALLISON POE; KATHY NOE, individually and on behalf of her minor son, CHRISTOPHER NOE; JANE MOE, Ph.D.; and RACHEL KOE, M.D.

Plaintiffs,

V.

KAY IVEY, in her official capacity as Governor of the State of Alabama; STEVE MARSHALL, in his official capacity as Attorney General of the State of Alabama; DARYL D. BAILEY, in his official capacity as District Attorney for Montgomery County; C. WILSON BAYLOCK, in his official capacity as District Attorney for Cullman County; JESSICA VENTIERE, in her official capacity as District Attorney for Lee County; TOM ANDERSON, in his official capacity as District Attorney for the 12th Judicial Circuit; and DANNY CARR, in his official capacity as District Attorney for Jefferson County.

Defendants.

Civil Action No. 2:22-cv-184-LCB

DECLARATION OF STEPHEN ROSENTHAL, MD, IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER & PRELIMINARY INJUNCTION

- I, Stephen M. Rosenthal, M.D., declare as follows:
- 1. I submit this expert declaration based upon my personal knowledge.
- 2. If called to testify in this matter, I would testify truthfully based on my expert opinion.

Qualifications and Experience

- 3. I am a pediatric endocrinologist and have been practicing medicine for over forty years. I received my medical degree from Columbia University, College of Physicians & Surgeons, in 1976, and completed a residency in Pediatrics there. I also completed a fellowship in Pediatric Endocrinology at the University of California, San Francisco ("UCSF").
- 4. In 2012, I co-founded the Child & Adolescent Gender Center ("CAGC") at UCSF. I am the Medical Director at the Center, as well as a Professor of Clinical Pediatrics at UCSF. A true and correct copy of my Curriculum Vitae is attached hereto as **Exhibit A**.
- 5. The Child and Adolescent Gender Center (CAGC) is a multidisciplinary program that provides comprehensive medical and mental health care, as well as education and advocacy services for transgender youth and adolescents. Since 2012, the CAGC has seen close to 2,000 transgender young people with gender dysphoria, with an average of 15-20 new patients per month, ranging in age from 3 to 25 years old. As Medical Director of the CAGC, I oversee

the medical portion of the multidisciplinary program, which currently includes two other physicians, a doctor of nursing practice, one psychologist, a clinical social worker, nursing, and administrative staff.

- 6. As of the date of this declaration, I have published 27 scientific research papers in leading peer-reviewed medical journals and authored seven chapters in authoritative textbooks on the topic of medical treatment for gender dysphoria in children and adolescents. Those publications include "Challenges in the Care of Transgender and Gender-Diverse Youth: An Endocrinologist's View," published in Nature Reviews Endocrinology¹ on August 10, 2021, "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," a guide detailing the standard of medical care for gender dysphoria, and a chapter in the forthcoming standards of care being developed by WPATH. A listing of my publications is included in my Curriculum Vitae in Exhibit A.
- 7. I am also actively serving as a Principal Investigator or Co-Investigator on numerous research projects on the physical and mental health of transgender young people, including a national multi-site study on medical care for transgender young people funded by the NIH.

¹ Nature Reviews Endocrinology received an impact factor of 43.33 for the 2021-2022 publication year.

- 8. I am a member and recent past president (2016-2017) of the Pediatric Endocrine Society and, as of March, 2021, have just completed a three-year term as a member of the Board of Directors for the Endocrine Society, and one-year term as Endocrine Society Vice President, Clinical Scientist Position. I am also an elected member of the Board of Directors of the World Professional Association for Transgender Health ("WPATH"), an international multidisciplinary professional association founded in 1979 to promote evidence-based care, education, research, advocacy, public policy and respect in transgender health. A complete list of my professional associations is included in my Curriculum Vitae in Exhibit A.
- 9. In addition to my work with transgender children and adolescents, I have treated children and adolescents with differences of sex development ("DSD"), commonly referred to as intersex conditions, as well as with a variety of other endocrine conditions, including growth disorders, pubertal disorders, and diabetes. I previously served as Program Director for Pediatric Endocrinology, Director of the Endocrine Clinics, and Co-Director of the Disorders of Sex Development Clinic, a multi-disciplinary program involving pediatric endocrinology, pediatric urology, psychiatry, and social work at UCSF Benioff Children's Hospital.
- 10. My opinions contained in this declaration are based on: (i) my clinical experience as a pediatric endocrinologist treating transgender patients, including adolescents and young adults; (ii) my knowledge of the peer-reviewed research,

including my own, regarding the treatment of gender dysphoria, which reflects the clinical advancements in the field of transgender health; and (iii) my review of the expert declaration of Linda A. Hawkins, Ph.D., M.S.Ed., LPC ("Dr. Hawkins Decl.") submitted in support of the motions. I generally rely on these types of materials when I provide expert testimony, and they include the documents specifically cited as supportive examples in particular sections of this declaration. The materials I have relied on in preparing this declaration are the same type of materials that experts in my field of study regularly rely upon when forming opinions on the subject.

- 11. I was provided with and reviewed the following case-specific materials: the Dr. Hawkins Decl.
 - 12. In the past four years, I have not provided expert testimony.
- 13. I am being compensated at an hourly rate for the actual time that I devote to this case, at the rate of \$350 per hour for any review of records, preparation of reports or declarations. I will be compensated with a day rate (6 hours) of \$2,100 for deposition and trial testimony. My compensation does not depend on the outcome of this litigation, the opinions that I express, or the testimony that I provide.

Scientific and Medical Understanding of Sex

14. By the beginning of the twentieth century, scientific research had established that external genitalia alone are not always an accurate indicator of a person's sex. Instead, a person's sex is comprised of several components, including,

among others, internal reproductive organs, external genitalia, chromosomes, hormones, gender identity, and secondary-sex characteristics. Diversity and incongruence in these components of a person's sex are a naturally occurring source of human biological diversity.

- 15. Scientific research and medical literature across disciplines demonstrate each component of sex has strong biological ties, including gender identity. For example, there are numerous studies detailing similarities in the brain structure and function of transgender and nontransgender people with the same gender identity. In one such study, the volume of the bed nucleus of the stria terminalis (a collection of cells in the central brain) in transgender women was equivalent to the volume found in nontransgender women. There are also studies highlighting the genetic components of gender identity. A study of identical twins found that if one twin was transgender that the other twin was far more likely to be transgender, as compared to the general population.
- 16. The above studies are representative examples of the growing body of scientific research and medical literature in this area of study. There is also ongoing research on the effects of the hormonal milieu in utero, and genetic sources for gender identity, among others.
- 17. Although the specific determinants of gender identity remain unknown, treatment to bring a person's physical characteristics into alignment with their

gender identity is widely accepted as the standard in medical practice.

Determination of an Individual's Sex

- 18. At birth, newborns are assigned a sex, either male or female, typically based solely on the appearance of their external genitalia. For most people, that assignment turns out to be accurate and their assigned sex matches that person's gender identity. However, for transgender people, their assigned sex does not align with their gender identity. This lack of alignment can create significant distress for transgender individuals.
- 19. When there is a divergence between these factors, medical science and the well-established standards of care recognize that treating a person consistent with their gender identity—and prescribing medical treatment to align their body with their gender identity—is essential to that person's health and wellbeing.
- 20. Gender identity is a person's inner sense of belonging to a particular gender, such as male or female. It is a deeply felt and core component of human identity. Everyone has a gender identity. Children usually become aware of their gender identity early in life.
- 21. A person's gender identity is innate, cannot be voluntarily changed, and is not undermined by the existence of other sex-related characteristics that do not align with it.
 - 22. Any attempts to "cure" transgender individuals by forcing their gender

identity into alignment with their assigned sex are harmful, dangerous, and ineffective. Those practices have been denounced as unethical by all major professional associations of medical and mental health professionals, such as WPATH, the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, and the American Psychological Association.

23. For more than four decades, the goal of medical treatment for transgender patients has been to alleviate their distress by bringing their lives into closer alignment with their gender identity. The specific treatments prescribed are based on individualized assessment conducted by medical providers in consultation with the patient's treating mental health provider. As discussed in more detail in the following section, and in the declaration of Dr. Hawkins, research and clinical experience have consistently shown those treatments to be safe, effective, and critical to the health and well-being of transgender patients.

Standards of Care for the Treatment of Gender Dysphoria

24. Due to the incongruence between their assigned sex and gender identity, transgender people experience varying degrees of "gender dysphoria," a serious condition listed in both the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders ("DSM-5") and the World Health Organization's International Classification of Diseases ("ICD-10"), and has been

recognized as such for decades. It is a condition that affects a small percentage of youth and adults.

- 25. Gender dysphoria is the diagnostic term for the clinically significant distress resulting from the incongruence between a person's gender identity and the sex they are assigned at birth. In order to be diagnosed with gender dysphoria, the incongruence must have persisted for at least six months and be accompanied by clinically significant distress or impairment.
- 26. Gender dysphoria is highly treatable and can be effectively managed. If left untreated, however, it can result in severe anxiety and depression, self-harm, and suicidality. Spack NP, Edwards-Leeper L, Feldmain HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012; 129(3):418-425. Olson KR, Durwood L, DeMeules M, McLaughlin KA. Mental health of transgender children who are supported in their identities. *Pediatrics*. 2016; 137:1-8.
- 27. The prevailing standards of care for the treatment of gender dysphoria are developed by WPATH, which has been recognized as the standard-setting organization for the treatment of gender dysphoria for more than forty years.
- 28. The Endocrine Society is a 100-year-old global membership organization representing professionals in the field of adult and pediatric endocrinology. In 2017, the Endocrine Society published its second clinical practice

guidelines on treatment recommendations for the medical management of gender dysphoria, in collaboration with Pediatric Endocrine Society, the European Societies for Endocrinology and Pediatric Endocrinology, and WPATH, among others. Hembree WC, Rosenthal SM, et al. Endocrine Treatment of Gender Dysphoria/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2017; 102: 3869–3903.

29. Together, the SOC and the Endocrine Society's clinical practice guidelines constitute the prevailing standards guiding the healthcare and treatment of gender dysphoria. The process for writing those standard-setting documents followed well-established methods for developing standards of care, beginning with the convening a core group of experts in the relevant field(s) who are tasked with conducting a comprehensive literature review and preparing a draft document. That draft is then circulated to a larger cross-section of practitioners in the relevant field(s) for review and comment, much like the peer-review process for journals. Those edits and comments are incorporated and compiled into a final document that is reviewed and ratified in a manner consistent with the organization's bylaws. As a result, the SOC and the Endocrine Society's clinical practice guidelines reflect the consensus of experts in the field of transgender medicine, based on the best available science and clinical experience.

- 30. The major professional associations of medical and mental health providers in the United States, including the American Medical Association, American Academy of Pediatrics, American Psychiatric Association, American Psychological Association, and Pediatric Endocrine Society, treat those documents as the prevailing standards guiding the healthcare and treatment of gender dysphoria.
- 31. Those documents help ensure that healthcare providers, especially those unfamiliar with transgender medicine, know which treatments are safe and effective for the treatment of gender dysphoria, and are able to deliver that necessary medical care to maximize their patients' overall health and wellbeing.

Transition and Medical Treatments for Gender Dysphoria

- 32. Undergoing treatment to alleviate gender dysphoria is commonly referred to as a transition. The transition process typically includes one or more of the following three components: (i) social transition, including adopting a new name, pronouns, appearance, and clothing, and correcting identity documents; (ii) medical transition, including puberty-delaying medication and hormone-replacement therapy; and (iii) surgical transition, including surgeries to alter the appearance and functioning of primary- and secondary-sex characteristics.
- 33. The steps that make up a person's transition will depend on that individual's medical and mental health needs, as well as the person's stage of pubertal development.

- 34. Dr. Hawkins provides an extensive discussion of social transition in her expert declaration. (Dr. Hawkins Decl. at ¶¶ 26–31.) My declaration will discuss the medications and surgical care used to treat gender dysphoria.
- 35. There are no drug interventions for gender dysphoria until after the onset of puberty. Medical providers evaluate a patient's level of pubertal development through a physical examination and testing the hormone levels in the patient's blood. Once a provider has determined that a transgender patient has begun puberty, the patient may be prescribed puberty-blocking medications.
- 36. Those medications work by temporarily pausing endogenous puberty and, therefore, limiting the influence of a person's endogenous sex hormones on their body. For example, a transgender girl (someone designated male at birth with a female gender identity) will experience no progression of physical changes caused by testosterone, including facial and body hair, an Adam's apple, a deepened voice, or masculinized facial structures. And in a transgender boy (someone designated female at birth with a male gender identity), those medications would prevent progression of breast development, menstruation, and widening of the hips. This prevents a transgender adolescent from experiencing the severe psychological distress of developing permanent, unwanted physical characteristics that do not align with the adolescent's gender identity.

- 37. Temporarily halting a transgender adolescent's pubertal development can also obviate the need for future surgical treatments to address any ongoing gender dysphoria. Avoiding the scarring associated with surgery—and the added stresses of surgery itself—further improve a transgender person's overall health and wellbeing.
- 38. A transgender adolescent will remain on those puberty-blocking medications until their providers determine, in consultation with the patient, the patient's family, and consistent with the prevailing standards of care, whether additional medical treatment is necessary to treat their gender dysphoria. If the decision is to stop taking puberty blockers, the patient's endogenous puberty will resume.
- 39. For many transgender youth, it is medically necessary for them to begin hormone-replacement therapy with either testosterone or estrogen. That treatment induces the physical changes of the puberty associated with the patient's gender identity. The result of this treatment is that a transgender boy has the same typical levels of circulating testosterone as his nontransgender male peers. Similarly, a transgender girl will have the same typical levels of circulating estrogen as her nontransgender female peers. Those hormones cause transgender adolescents to undergo the same significant and permanent sex-specific physical changes as their nontransgender peers. For example, a transgender boy will develop a lower voice as

well as facial and body hair, while a transgender girl will experience breast growth, female fat distribution, and softer skin.

- 40. If a transgender youth who is on puberty blockers and hormonereplacement therapy ceases these medications, the production of endogenous hormones and puberty consistent with the individual's birth sex will resume.
- 41. Puberty-delaying medication and hormone-replacement therapy—both individually and in combination—also significantly improve a transgender young person's mental health because those medications ensure their physical appearance more closely aligns with their gender identity. This also decreases the likelihood that a transgender young person will be incorrectly identified with their birth sex, further alleviating their gender dysphoria and bolstering the effectiveness of their social transition.
- 42. The puberty-delaying medications that are used for treating transgender children are the same medications that have been used for decades and are continued to be used to treat a condition in children often referred to as "precocious puberty," a condition that causes a child's body to begin pubertal development too early. In other words, the hormone therapy used to treat transgender adolescents is often used to treat non-transgender adolescents for other medical reasons.
- 43. Social transition and hormone therapy are often sufficient to treat gender dysphoria for many transgender people.

- 44. Based on my clinical experience, there are transgender young people for whom getting on puberty blockers and hormones before the age of majority will reduce the likelihood of their needing surgical intervention later in life relating to gender dysphoria.
- 45. Further, recent studies have observed findings that gender-affirming hormone therapy usage is significantly related to lower rates of depression and suicidality among transgender youth. Green AE et al. Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. *J Adolescent Health* 1-7 (2021); Turban JL et al. Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. PLoS ONE 17(1) 2021; https://doi.org/10.1371/journal.pone.0261039.
- 46. For transgender people who require surgery to treat their gender dysphoria, the SOC do not recommend surgical treatment until the age of majority, except for male chest reconstruction surgery. Like any other treatment, the medical necessity of surgical procedures to treat gender dysphoria is based on an individualized assessment of the patient's needs.

Assessing Medical Necessity of Medical Treatment for Gender Dysphoria

47. As with the initial diagnosis of gender dysphoria, determining whether a particular treatment is medically necessary for a transgender patient follows a

thorough, well-established process that requires healthcare providers to exercise professional judgment. Contrary to what some believe, prescriptions for puberty-blocking medication and hormone-replacement or referrals for surgery are not made on a whim. Every step of a transgender patient's treatment and care is planned out in consultation with the patient's care team, which includes both medical and mental health providers.

- 48. Prior to considering starting a course of puberty-blockers or hormone-replacement therapy, a transgender patient undergoes an extensive assessment by a mental health provider. The purpose of that assessment is three-fold: (1) obtaining a complete picture of the patient's mental health, including whether the patient has gender dysphoria; (2) determine the patient's psychological readiness to begin the contemplated treatment; and (3) provide the patient and their family the information they need to make an informed decision about whether to proceed with the treatment. If, after that assessment, the mental health provider determines that the patient should be considered for the contemplated treatment, that professional opinion is documented in a letter to the patient's medical provider.
- 49. The medical provider then conducts their own separate assessment of the patient, including a physical examination and any necessary laboratory testing. In addition to determining the medical necessity of the contemplated treatment and a patient's medical readiness for that treatment, the medical provider will also

discuss the risks, benefits, and alternatives for the contemplated treatment. Medical providers also discuss with parents that the medications are being prescribed for an off-label use, which is particularly common for medications being used in pediatric patients. That discussion occurs with the patient and their family to ensure that everyone involved in the decision-making process has the information they need to make an informed decision.

- 50. Once the medical provider has finished addressing any questions or concerns raised by the patient and family, the parents/legal guardians and the patient are provided with a detailed informed consent/assent form that outlines in writing the information the medical provider reviewed with them. The patient and family are encouraged to carefully review that paperwork and sign if they choose to consent/assent to treatment.
- 51. It is only at the end of that intensive assessment and informed-consent process that a patient is prescribed a particular medical treatment for gender dysphoria.

Medical Treatment for Gender Dysphoria is Evidence-Based Medicine

- 52. Research and clinical experience repeatedly reaffirm that transition significantly improves the mental and physical health of transgender young people.
- 53. This is true of each stage of a transgender young person's transition.

 Transgender young people who underwent a social transition in childhood

demonstrated better mental health profiles than prior studies of gender nonconforming children. See Lily Durwood, et al., Mental Health and Self-Worth in Socially Transitioned Transgender Youth, 56 J. Am. Acad. of Child & Adol. Psychiatry 116 (2017); Kristina Olson, et al., Mental Health of Transgender Children who are Supported in Their Identities, 137 Pediatrics 1 (2016). This same outcome has also been seen in a longitudinal study of transgender young people who underwent each of the three stages of transition outlined above. Annelou L.C. de Vries, et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 134 Pediatrics 696 (2014). In a study specifically about male chest reconstruction surgery, post-operative transgender young people demonstrated significant psychological and functional improvements, from a greater willingness to plan for their future and to engage activities of daily living (e.g., bathing, buying clothing). Johanna Olson-Kennedy, et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts, 172 JAMA Pediatrics 431, 434 (2018)

54. Transition also can—and often does—alleviate co-occurring mental health issues a transgender young person experienced prior to transition. Following transition, transgender young people typically see significant improvements in functioning and quality of life. Treating their gender dysphoria also increases a

transgender young person's capacity to develop and maintain better coping strategies to manage any co-occurring conditions.

55. Conversely, delaying or denying transgender young people safe and effective treatment for gender dysphoria—as contemplated by the wait-and-see approach—can have severe consequences on their physical and mental health. Without those medically necessary treatments, transgender young people are likely to develop serious co-occurring mental health conditions (*i.e.* anxiety, depression, suicidality) that will interfere with their ability to learn and impede their psychosocial development.

Conclusion

- 56. Alabama's law criminalizing the provision of medical treatment for gender dysphoria is contrary to well-established standards of care, peer-reviewed medical literature, and clinical experience. Medical care for transgender young people in Alabama would be guided by fear of criminal penalty, forcing medical providers to abandon their professional and ethical obligations to follow the prevailing standards of care when treating patients with gender dysphoria.
- 57. Contrary to its stated purpose, this bill will endanger the health and wellbeing of transgender young people experiencing gender dysphoria by creating significant barriers to their receiving medically necessary care. The lack of access to

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that time-sensitive care will have lifelong implications for their quality of life and their ability to effectively treat their gender dysphoria.

This declaration was executed this 19th day of April, 2022.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

By: Stephen M. Rosenthal, M.D.